

**AGRICULTURE, RURAL DEVELOPMENT, FOOD AND  
DRUG ADMINISTRATION, AND RELATED AGEN-  
CIES APPROPRIATIONS FOR FISCAL YEAR 2016**

---

**HEARINGS**

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

FIRST SESSION

ON

**H.R. 3049/S. 1800**

AN ACT MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES PROGRAMS FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2016, AND FOR OTHER PURPOSES

---

**Department of Agriculture  
Department of Health and Human Services: Food and Drug  
Administration**

---

Printed for the use of the Committee on Appropriations



Available via the World Wide Web: <http://www.gpo.gov/fdsys/browse/committee.action?chamber=senate&committee=appropriations>

---

U.S. GOVERNMENT PUBLISHING OFFICE

24-506 PDF

WASHINGTON : 2017

---

For sale by the Superintendent of Documents, U.S. Government Publishing Office  
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800  
Fax: (202) 512-2104 Mail: Stop IDCC, Washington, DC 20402-0001

## COMMITTEE ON APPROPRIATIONS

THAD COCHRAN, Mississippi, *Chairman*

MITCH McCONNELL, Kentucky	BARBARA A. MIKULSKI, Maryland, <i>Vice</i>
RICHARD C. SHELBY, Alabama	<i>Chairwoman</i>
LAMAR ALEXANDER, Tennessee	PATRICK J. LEAHY, Vermont
SUSAN M. COLLINS, Maine	PATTY MURRAY, Washington
LISA MURKOWSKI, Alaska	DIANNE FEINSTEIN, California
LINDSEY GRAHAM, South Carolina	RICHARD J. DURBIN, Illinois
MARK KIRK, Illinois	JACK REED, Rhode Island
ROY BLUNT, Missouri	JON TESTER, Montana
JERRY MORAN, Kansas	TOM UDALL, New Mexico
JOHN HOEVEN, North Dakota	JEANNE SHAHEEN, New Hampshire
JOHN BOOZMAN, Arkansas	JEFF MERKLEY, Oregon
SHELLEY MOORE CAPITO, West Virginia	CHRISTOPHER A. COONS, Delaware
BILL CASSIDY, Louisiana	BRIAN SCHATZ, Hawaii
JAMES LANKFORD, Oklahoma	TAMMY BALDWIN, Wisconsin
STEVE DAINES, Montana	CHRISTOPHER MURPHY, Connecticut

BRUCE EVANS, *Staff Director*

CHARLES E. KIEFFER, *Minority Staff Director*

---

## SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

JERRY MORAN, Kansas, *Chairman*

ROY BLUNT, Missouri	JEFF MERKLEY, Oregon
THAD COCHRAN, Mississippi	DIANNE FEINSTEIN, California
MITCH McCONNELL, Kentucky	JON TESTER, Montana
SUSAN M. COLLINS, Maine	TOM UDALL, New Mexico
JOHN HOEVEN, North Dakota	PATRICK J. LEAHY, Vermont
STEVE DAINES, Montana	TAMMY BALDWIN, Wisconsin
	BARBARA A. MIKULSKI, Maryland
	<i>(ex officio)</i>

### *Professional Staff*

CARLISLE CLARKE

PATRICK CARROLL

RACHEL SANTOS

JESSICA ARDEN SCHULKEN *(Minority)*

DIANNE NELLOR *(Minority)*

### *Administrative Support*

TERI CURTIN *(Minority)*

## CONTENTS

---

THURSDAY, MARCH 12, 2015

	Page
Department of Health and Human Services: Food and Drug Administration ...	1

TUESDAY, MARCH 17, 2015

Department of Agriculture .....	51
---------------------------------	----

WEDNESDAY, SEPTEMBER 16, 2015

FDA Food Supply Safety Efforts .....	115
--------------------------------------	-----

WEDNESDAY, OCTOBER 21, 2015

A Review of Rural Development in 21st Century America .....	159
---	-----



**AGRICULTURE, RURAL DEVELOPMENT, FOOD  
AND DRUG ADMINISTRATION, AND RE-  
LATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 2016**

---

**THURSDAY, MARCH 12, 2015**

U.S. SENATE,  
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,  
*Washington, DC.*

The subcommittee met at 10 a.m. in room SD-138, Dirksen Senate Office Building, Hon. Jerry Moran (chairman) presiding.

Present: Senators Moran, Blunt, Hoeven, Daines, Merkley, Tester, and Leahy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

STATEMENT OF HON. DR. MARGARET A. HAMBURG, COMMISSIONER,  
FOOD AND DRUG ADMINISTRATION

ACCOMPANIED BY:

JAY TYLER, CHIEF FINANCIAL OFFICER, FOOD AND DRUG ADMINISTRATION

NORRIS COCHRAN, DEPUTY ASSISTANT SECRETARY FOR BUDGET,  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING STATEMENT OF SENATOR JERRY MORAN

Senator MORAN. Good morning, everyone. We are delighted to have you with us. My first faux pas as new subcommittee chairman was to fail to turn on the mike. Senator Blunt is here to correct any of those mistakes, and I look forward to working with Senator Merkley to see that our subcommittee does its oversight work and its appropriations process oversight in a very significant and meaningful way.

We are delighted to be here this morning. Today's hearing is going to focus on one of the important aspects of our subcommittee, the Food and Drug Administration (FDA), its fiscal year 2016 budget request. We thank the Commissioner, as I indicated, for being here, along with Mr. Tyler and Mr. Cochran.

We look forward to questioning you, Dr. Hamburg, with this being your last appearance before the subcommittee, and let me take a moment to thank you for your public service and wish you well. We look forward to your testimony today and we look forward to your success and enjoyment in the future.

The agency you head has authority over approximately 20 cents of every \$1 spent in America. Americans expect that the food they eat and the drugs they take will be safe and effective, and the FDA has vast reach.

The agency has authority over more than 300,000 foreign establishments and 185,000 domestic establishments, ranging from food processing plants to facilities that manufacture life-saving medications.

In addition to the facilities themselves, FDA is tasked with the regulatory responsibility of individual products. Just last week, FDA approved the first biosimilar product in the United States, enabling access to important therapies for patients in chemotherapy and other cancer treatments.

In delivering these regulatory responsibilities, your private sector partners expect transparency and certainty from the FDA, and when I speak to small businesses, agriculture producers in Kansas and across the country, their great concern is the limits of Government and how it limits their ability to create jobs and stifles innovation through unnecessary and burdensome regulations.

In part, we are here to try to eliminate where possible that unnecessary burden.

Over the past 4 years, the FDA has been given significant new responsibilities, including the Food Safety Modernization Act (FSMA), menu labeling legislation, and drug compounding legislation. When implementing these laws, FDA must avoid the trappings of one size solution fits all problems. Small business and consumers suffer under the practices that limit the ability to respond to new requirements and little time to implement those changes.

The agency's final rule on menu labeling in my view is overly broad and inflexible and lacks a great deal of practicality, and I was disappointed to see the inclusion of grocery stores, convenience stores, and other entities that do not sell restaurant style food as their primary business included in that regulation.

Under the Food Safety Modernization Act, FDA is tasked with implementing the most sweeping changes to food safety laws in over 70 years. I was pleased to see that the agency took many of the concerns within the agriculture community into account by re-proposing significant portions of the rules because they were unworkable for farmers.

With the court mandated deadline for finalization approaching, I encourage FDA to consider deliberate and thoughtful implementation of this law.

I look forward to discussing with you these and other topics this morning. We have a lot to cover. I will now turn to Senator Merkley.

[The statement follows:]

#### PREPARED STATEMENT OF SENATOR JERRY MORAN

This hearing will come to order. Good morning. Today's hearing will focus on the Food and Drug Administration's (FDA) fiscal year 2016 budget request, and thank you Commissioner Hamburg, Mr. Tootle, and Mr. Cochran for being here today to discuss FDA's priorities for the upcoming year. Dr. Hamburg, with this being your last appearance before the subcommittee as FDA Commissioner, I want to thank

you for your public service and your efforts to promote the health and safety of American consumers.

The agency you head has authority over approximately 20 cents of every \$1 spent in America. Americans expect that the food they eat and the drugs they take will be safe and effective. FDA's reach is vast; the agency has authority over more than 300,000 foreign establishments and 185,000 domestic establishments, ranging from food processing plants to facilities that manufacture lifesaving medications. In addition to facilities themselves, FDA is tasked with the regulatory responsibility of individual products. Just last week, FDA approved the first biosimilar product in the United States, enabling access to important therapies for patients in chemotherapy and other cancer treatments.

In delivering these regulatory responsibilities, your private sector partners expect transparency and certainty from FDA. When I speak to small businesses and agricultural producers in Kansas, their overwhelming concern is a government that limits their ability to create jobs and stifles innovation through unnecessary and burdensome regulations. We must always be mindful of these concerns.

Over the past 4 years, FDA has been given significant new responsibilities through the Food Safety Modernization Act, menu labeling legislation, and drug compounding legislation.

When implementing these laws, FDA must avoid the trappings of "one-size-fits-all" solutions. Small businesses suffer under this practice all too frequently because they have limited capital to respond to significant new requirements and little time to implement these changes.

The agency's final rule on menu labeling is overly broad and inflexible and lacks a great deal of business practicality. I was disappointed to see the inclusion of grocery stores, convenience stores, and other entities that do not sell restaurant style food as their primary business.

Under the Food Safety Modernization Act, FDA is tasked with implementing the most sweeping changes to food safety laws in over 70 years. I was pleased that the Agency took many of the concerns within the agricultural community into account by re-proposing significant portions of the rules because they were unworkable for farmers. With the court-mandated deadlines for finalization approaching, I encourage FDA to consider deliberate and thoughtful implementation of the law.

I look forward to discussing this and other topics with our witnesses today. We have a lot to cover this morning, so I will turn it over to Senator Merkley for his opening remarks.

#### STATEMENT OF SENATOR JEFF MERKLEY

Senator MERKLEY. Thank you very much, Mr. Chairman. I am delighted to be here in the role of ranking member, and I am certainly looking forward to working with you as we examine the budgets for the Department of Agriculture and the FDA.

Commissioner Hamburg, welcome to what is your last appearance before this subcommittee.

Senator MORAN. She is smiling.

Senator MERKLEY. You look a little too happy. You have had the longest tenure of any FDA Commissioner in recent history, so thank you for your service over the last 6 years. You have steered the FDA through a period of enormous growth in both funding levels and responsibilities.

In 2009, FDA's budget was just over \$2 billion in appropriated funds. In 2015, \$2.6 billion. If you throw in user fees on top of that, the numbers are even higher.

Since you took the helm, Congress has passed several major pieces of legislation including the Family Smoking Prevention and Tobacco Control Act, the Food Safety Modernization Act, Drug Quality and Security Act, and the FDA Safety and Innovation Act, each of which has placed significant new responsibilities on the agency, and each of which you are currently implementing.

At the end of the fiscal year, multiple new food safety rules will be finalized. I am hopeful that we will see the long awaited tobacco

deeming regulations from FDA in the next couple of months. There is a lot going on, and your leadership will be missed.

I am going to try to wrap this up fairly quickly so we can get to questions. I do want to point out this is a very robust budget request. The budget for FDA includes an increase of \$147 million in appropriated funding, with much but not all directed to food safety activities.

I know that this subcommittee has been critical of FDA budgets in recent years that have simply proposed new user fees to fund food safety activities, and the likelihood of approval of those fees was minimal.

This budget does have some additional proposed user fees, but also a significant budget authority increase of \$109 million for FSMA implementation, and an increase of \$15 million for the administration's larger combating antibiotic resistance initiative or CARB initiative regarding antimicrobial resistance.

While the FDA's piece of this is small, the role that FDA plays in ensuring there are new antibacterial drugs is vital. It is a significant issue, and I am pleased to see that you are addressing it in the budget, and look forward to your testimony. Thank you, Senator.

Senator MORAN. Senator Merkley, thank you. I, too, look forward to working with you, and Dr. Hamburg, we are now ready for your testimony.

Dr. HAMBURG. Thank you very much, and good morning, Chairman Moran—I have the same problem. Six years and I still have not learned——

Senator MORAN. Thank you for making me comfortable.

#### SUMMARY STATEMENT OF HON. DR. MARGARET A. HAMBURG

Dr. HAMBURG. Thank you, Chairman Moran, Ranking Member Merkley, and members of the subcommittee. I am pleased to be here today to discuss the President's fiscal year 2016 budget request for FDA. It is an important budget request, as Senator Merkley noted.

This will be my final appearance before the subcommittee before stepping down as Commissioner, and I want to begin by thanking this subcommittee for your past investments in FDA.

This support has helped us address many of the demands of our broad and ever more complex mission. I have appreciated the constructive dialogue that we have been able to have over the years.

During my tenure at FDA, Congress has recognized the vital and unique role that we play in promoting and protecting public health. Landmark new legislation has expanded FDA's authority as was just noted.

We now regulate tobacco products, implement legislation to dramatically transform our food safety system, and to expand our medical product mandates, and a host of other new programs as well, not to mention new requirements to ensure the safety and integrity of complex global supply chains for both medical products and for food.

Our accomplishments really demonstrate our ability to respond to evolving public health needs and responsibilities across the very broad spectrum of products that we regulate.

However, resources in fact have not kept pace with our new authorities and mandates, as well as the demands of dramatic advances in the science and technology that underpins the products that we regulate, and the rapidly changing global marketplace, which has enormous ramifications on the work that we do and the people we work to protect.

Moreover, most of our growth in funding has been in user fees provided by regulated industries, resources that can be spent only on a limited range of FDA programs.

We certainly recognize the duty that you have to wisely distribute taxpayer dollars among many competing priorities, but FDA has had a great return on investment.

Last year, in terms of budget authority, FDA cost every American only about \$8 to ensure the safety of their food, their access to safe, effective, and even life-saving medical products, a safe blood supply, and so much more.

FDA is committed to finding efficiencies wherever they exist. In fact, in the budget before you, we are proposing \$16 million in reductions to our base resources, nonetheless, tackling such critical challenges as food safety modernization, antibiotic resistance, and precision medicine requires additional investments at this time.

#### BUDGET REQUEST

To help meet our public health mission for fiscal year 2016, FDA is requesting \$4.9 billion, \$2.7 billion in budget authority, and \$2.2 billion in user fees. The increase above fiscal year 2015 is \$425 million, \$148 million of which is budget authority. Again, recognizing the larger pressures on the Federal budget, we focused the budget request on essential functions and urgent needs of our agency.

I would like first to address FDA's efforts to improve and protect America's food supply. The fiscal year 2016 budget request includes a total of \$1.5 billion for food safety and nutrition, including \$109.5 million budget authority increase. This increase will be largely dedicated to implementation of the Food Safety Modernization Act or FSMA.

Since FSMA was passed in 2011, FDA has made extraordinary progress, including the issuance of seven major proposed regulations which will be finalized later this year.

Significant funding gaps still loom. The actual on the ground implementation of these regulations will require us to modernize inspections and retrain staff to apply the new rules effectively and consistently, provide guidance and technical assistance to industry to support their compliance efforts, and invest in the capacity of our State partners to leverage their local knowledge and capacity.

We also must address concerns about the safety of the large and growing volume of food imported from other countries. FSMA empowers the agency to hold foreign food producers to the same standards we expect of food producers in the United States. We must do so to ensure a level playing field for American firms, and most importantly, to protect our citizens.

I cannot overstate the importance of our request to fund continued successful implementation of FSMA. A shortfall in funding will undermine Congress' intent to transform our Nation's food safety program, and will harm all stakeholders.

If we invest now, I am confident that we can fulfill FSMA's vision of a modern prevention oriented food safety system that works collaboratively across our global food system to reduce foodborne illness, bolstering public confidence in the food supply, and maintaining U.S. leadership on food safety.

In the vital area of medical product safety and innovation, the fiscal year 2016 budget request provides a program level of \$2.7 billion, including a budget authority increase of \$33.2 million above fiscal year 2015.

Part of the proposed budget increase will support FDA implementation of key initiatives of FDASIA, the Food and Drug Administration Safety and Innovation Act, and to continue important work on the national strategy for combating antibiotic resistant bacteria, where we have made important strides on both the human and the animal front, although this remains a pressing public health challenge.

An additional \$10 million is to support FDA's essential role in personalized or precision medicine, and enable us to continue to speed the development of promising new diagnostics and treatments for patients with serious illnesses.

Our exciting work in medical product innovation and safety is a testament both to the new opportunities that have been presented by scientific knowledge and technology, as well as our innovative approaches to expedite development and review of medical products to address unmet medical needs while adhering to established standards for safety and efficacy.

In fact, in 2014, FDA approved the most new drugs and biologics in almost 20 years, and brought life-saving drugs to market more quickly than ever. We have also made real progress in reducing times for medical devices to reach the market.

Enhanced funding will help us to maintain our Nation's preeminence in biomedical product innovation and safety, and will benefit us all.

Let me close by underscoring that FDA's public health mission is indispensable to the health and well being of every American. We carry out our mission effectively and with relatively few taxpayer dollars, despite tremendous expansions in our responsibilities as a result of new legislation, scientific and technological advances, and a globalized marketplace.

Our budget request plans for efficient spending on programs that are essential to providing Americans with safe foods and safe and effective medical products that they expect and count on.

I know that with your ongoing support, FDA will continue to move forward in fulfilling its critical responsibilities to the American public.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF HON. DR. MARGARET A. HAMBURG

#### INTRODUCTION

Good morning Chairman Moran, Ranking Member Merkley, and members of the subcommittee, I am Dr. Margaret Hamburg, Commissioner of the Food and Drug Administration (FDA). Thank you for the opportunity to appear before you today to discuss the President's fiscal year 2016 budget request for FDA. I would like to thank the subcommittee for its past investments in FDA, which have helped us

meet the demands of our broad and increasingly complex mission. For fiscal year 2016, FDA is requesting \$4.9 billion to support our essential functions and priority needs.

On a personal note, I'd like to thank the Committee for its continuing commitment to these issues during my 6 years as Commissioner. As you know, I will be stepping down at the end of this month, so this will be my final appearance before this subcommittee. I will miss the constructive dialogue we have enjoyed over the years to address matters of mutual concern. My decision to leave FDA was not an easy one, as there is always more to be done, and I remain dedicated to the vital work and mission of the agency. But, I am confident that I leave the agency stronger and more effective than when I began, and better positioned to meet the challenges of the 21st century. And, I know that with your commitment, FDA will continue to move forward in fulfilling its critical responsibilities to the American public.

#### FDA PLAYS A VITAL ROLE IN AMERICA'S PUBLIC HEALTH SYSTEM

FDA is a science-based regulatory agency charged with an enormous and significant public health mission: to promote and protect the health of the American people. Our goal in carrying out our mission is to ensure the safety, effectiveness, and quality of medical products, as well as the safety and security of the vast majority of our Nation's food supply. The agency also regulates the manufacturing, marketing, and distribution of tobacco products and seeks to reduce the use of tobacco products by minors. FDA plays a unique and vital role in facilitating the availability of safe and effective products, while also protecting citizens from products that may cause harm.

FDA's important work promotes innovation in the industries it regulates, creates jobs, and positions domestic industries to compete in the global marketplace. History shows that when there is public trust in FDA's oversight, the industries we regulate flourish. Conversely, when food and medical products cause serious harm, the result is often severe economic damage across the industry involved.

Congress has recognized the dynamic role that FDA plays and the increasingly complex and global environment in which we operate. As a result, FDA has been tasked with a multitude of new responsibilities and authorities in the public health arena, including the Drug Quality and Security Act (DQSA); the FDA Safety and Innovation Act (FDASIA); the FDA Food Safety Modernization Act (FSMA); and the Family Smoking Prevention and Tobacco Control Act. While FDA has stepped up to meet these essential public health challenges under current funding levels, successful implementation of these new authorities requires significant additional resources.

#### FDA HAS A PROVEN TRACK RECORD OF SUCCESS

FDA's accomplishments over the past year have been as substantial as any in the agency's recent history. Across the areas of food safety and nutrition, medical product safety and innovation, tobacco control, and other areas of our work, our accomplishments demonstrate our ability to respond to evolving needs and opportunities—including the embrace of new approval pathways, innovative technologies, and cutting-edge science.

Moreover, especially given the importance of our work, FDA is a bargain. The products regulated by FDA account for more than 20 percent of every consumer dollar spent on products in the United States but individual Americans only pay about 2 cents per day to ensure that those products are safe and effective. This is a small price for life-saving medicines approved as fast or faster than anywhere in the world, confidence in medical products that are relied on daily, and a food supply that is among the safest in the world.

#### FDA'S INNOVATIONS IMPROVE AND PROTECT AMERICA'S FOOD SUPPLY

*Food Safety Modernization.*—FDA published seven major proposed rules and, based on stakeholder input, four supplemental proposals to implement FSMA. The agency also completed 8,607 high-risk food establishment inspections in fiscal year 2014, exceeding the target of 6,507 inspections by 32 percent. FDA also released a FSMA Operational Strategy Document that focuses on how we can implement FSMA by prioritizing prevention, voluntary compliance, risk-based oversight, and expanded collaboration across the food safety community.

*Genome-Based Food Pathogen Detection.*—FDA established GenomeTrakr, the first national pilot network of whole genome sequencers (WGS) for pathogen identification to trace where outbreaks start—even at the level of a single farm or food facility—based on whole bacterial genomes. FDA is already utilizing this innovative technology, such as in the identification and closure of a cheese facility connected

to a *Listeria monocytogenes* outbreak, to take quicker, yet more targeted, action and likely prevent a larger number of illnesses.

*Nutrition Labeling.*—On December 1, 2014, FDA published two final rules requiring that calorie information be listed on menus and menu boards in chain restaurants and similar retail food establishments, and on signs for vending machines. Americans eat and drink about one-third of their calories away from home, and this is an important public health step to help consumers make informed choices for themselves and their families. FDA also proposed important updates to the nutrition facts label, such as more prominent calorie declarations, to bring it up to date with current diet and health concerns.

#### PROMOTING INNOVATIVE MEDICAL PRODUCT DEVELOPMENT

*Medical Product Application Review.*—FDA’s rapid drug reviews and use of expedited programs has helped provide meaningful new products to U.S. patients. In 2014, FDA approved 51 new molecular entities and biological products, more than in any single year in almost 20 years. Among the 2014 approvals are treatments for cancer, hepatitis C and type-2 diabetes, as well as the most new drugs for “orphan” diseases since Congress approved the Orphan Drug Act more than three decades ago. Seventeen of the new approvals are “first in class” therapies, which represent new approaches in the treatment of disease, and almost two-thirds were approved first in the United States. In addition, important biological products approved in 2014 include a number of groundbreaking vaccines for meningitis B, the flu, and certain types of human papillomavirus.

From 2011 to 2014, the median number of days for FDA to approve investigational device exemption (IDE) submissions decreased from 442 to only 101, cutting the time it takes to bring a new medical device to market by nearly a full year. In addition, improvements to the de novo program have resulted in a 70-percent reduction in the average total time to decision for these submissions.

These developments are a testament not just to expanding understanding of human biology and the molecular mechanisms that drive the disease process, but also to FDA’s innovative approaches to help expedite development and review of medical products that target unmet medical needs, while adhering to the established standards for safety and efficacy.

*Abuse-Deterrent Opioid Medications.*—FDA continues to make progress in its efforts to help reduce prescription drug abuse, while remaining committed to ensuring that patients with pain have appropriate access to medicines they need. In 2014, FDA approved three new opioids with abuse deterrent features to give physicians effective new treatment options with less risk of abuse. To help encourage the development of more abuse-deterrent formulations of opioids, the agency hosted a public meeting to discuss scientific and technical issues related to development and assessment of abuse-deterrent opioid products and is working diligently to finalize its guidance on this topic this spring. We also approved a new dosage form of naloxone with an autoinjector to allow for the emergency treatment of opioid overdoses in community settings.

*Drug Quality and Security Act.*—During fiscal year 2014, FDA conducted over 90 inspections of compounding facilities, issued warning letters, and worked with DOJ to bring criminal and civil enforcement actions. The agency also continued to develop a framework to implement the new law. FDA has issued numerous policy documents to implement Federal Food, Drug, and Cosmetic Act section 503A, as amended by the DQSA, as well as section 503B, as added by DQSA, concerning outsourcing facilities. In addition, on February 23–24, 2015, FDA held the first meeting of the Pharmacy Compounding Advisory Committee to provide advice on scientific, technical, and medical issues concerning drug compounding.

#### FDA WORKS TO REDUCE THE IMPACT OF TOBACCO ON THE PUBLIC HEALTH

*Family Smoking Prevention and Tobacco Control Act.*—FDA published the proposed “deeming rule” to extend FDA’s tobacco authority to additional tobacco products, including e-cigarettes, and is reviewing over 135,000 comments the agency received in preparation of the final rule. Public health-based regulation of these products can help reduce the death and disease toll from tobacco use. FDA also closely monitors retailers’ compliance with restrictions on tobacco product marketing and sales to youth—and takes strong corrective action when violations occur. In addition, the agency launched a major public education campaign targeting youth about the dangers of tobacco products, with the goal of reducing or preventing use in future generations.

## FDA TACKLES EMERGING, UNIQUE, AND COMPLEX CHALLENGES

*Combating Antimicrobial Resistance.*—FDA has made important strides in confronting the growing resistance of some bacteria to antimicrobial drugs. In 2014, FDA approved four novel systemic antibiotics to expand the pipeline of new medical products available for identification, prevention, treatment, and/or cure of bacterial infections. In contrast, only five new antibiotics had been approved in the previous 10-year period. In addition to working on the human medical product side, FDA has made great progress on its initiative to fight antimicrobial resistance by restricting the use of medically important antimicrobials in food animal production to legitimate animal health purposes. All 26 drug companies with affected products have committed in writing to remove animal production uses from their FDA-approved labels and bring the remaining medical uses under veterinary supervision by the end of 2016. FDA is working closely with USDA, producers and drug companies to support implementation of these important changes and gather data to verify their effectiveness in reducing antimicrobial resistance.

*Ebola Outbreak Response.*—In response to the Ebola epidemic in West Africa, FDA has acted aggressively to help expedite the development and availability of investigational medical products for Ebola, including by: providing regulatory advice and guidance to commercial developers and U.S. agencies; helping to facilitate access to investigational medical products for patients with Ebola when requested by clinicians; and authorizing the use of eight investigational diagnostic tests for Ebola under FDA's Emergency Use Authorization authority. We have collaborated extensively with the World Health Organization, NGOs and several international regulatory counterparts to support international response efforts. FDA has also monitored for fraudulent products that claim to prevent, treat, or diagnose Ebola and took action, as warranted, to protect public health.

## FDA'S FISCAL YEAR 2016 PRESIDENT'S BUDGET REQUEST

The fiscal year 2016 President's budget request for FDA is \$4.9 billion for the total program level, which is \$425 million above the fiscal year 2015 enacted level. Of the total funding, \$2.7 billion is budget authority and \$2.2 billion is user fees. The fiscal year 2016 increase consists of \$148 million in budget authority and \$277 million in user fees. The growth in user fee funding stems from several new programs, along with increased collection authority for many of FDA's existing programs. Mindful of the larger pressures on the Federal budget, we have focused our request on the most urgent needs for fiscal year 2016.

## FOOD SAFETY

The fiscal year 2016 budget provides a total program level of \$1.5 billion for food safety, which is \$301 million above the fiscal year 2015 enacted level. This total includes a \$109.5 million increase in budget authority and a \$191.8 million increase in user fees. The proposed budget authority increase will be almost exclusively dedicated to implementation of FSMA.

FDA's successful implementation of FSMA is essential to reducing foodborne illness, bolstering public confidence in the food supply, and maintaining U.S. leadership on food safety internationally. With FDA under court order to issue many key FSMA regulations in 2015, fiscal year 2016 is an absolutely crucial year for the investments needed to ensure timely, effective, and non-disruptive implementation. FDA's collaborative implementation strategy requires a modernized approach to inspection and enforcement, focusing on food safety outcomes and encouraging voluntary compliance. To be successful, this strategy requires retraining and retooling of FDA and State inspectors. In keeping with FSMA's theme of collaboration and partnerships, the largest single portion of the budget authority will go to the States to better integrate, coordinate, and leverage Federal and State food safety efforts.

FDA's FSMA philosophy of "educate before and while we regulate" also requires investing in guidance, education, and technical assistance for industry to support their compliance efforts, especially among smaller scale farmers and manufacturers. FDA will deliver this assistance through collaborative alliances and training partnerships.

Finally, FDA must make crucial investments in fiscal year 2016 to implement the new import safety system mandated by Congress. This includes FSMA's Foreign Supplier Verification Program requirements, which are the foundation for FSMA's new import safety system and key to helping assure a level playing field of food safety standards and oversight for U.S. consumers and industry.

The investments FDA can make with the fiscal year 2016 budget authority request will enable the agency to maintain momentum toward timely and successful

implementation of FSMA. Without these investments, implementation will be disrupted and delayed.

#### MEDICAL PRODUCT SAFETY AND INNOVATION

The fiscal year 2016 budget provides a program level of \$2.7 billion, which is \$84.8 million above the fiscal year 2015 enacted level, to continue core medical product safety activities across FDA programs.

With part of this increase, FDA will support implementation of three initiatives of FDASIA: the Unique Facility Identifier; Unique Device Identifier; and Electronic Biological Product Application Submission programs. FDA will also continue contributing to the National Strategy for Combating Antibiotic-Resistant Bacteria (CARB) to help ensure the judicious use of medically important antimicrobials in food-producing animals; to evaluate new antibacterial drugs for patient treatments; to streamline clinical trials; and to develop better vaccines for antibiotic resistant organisms. An increase of approximately \$1 million will support continued implementation of new compounding oversight authorities and the evaluation of sunscreen ingredients. Finally, \$10 million of the increase will help FDA adapt its regulatory process to developments in "precision medicine." Funding this initiative will permit FDA to keep pace with scientific advancements and help speed the development of promising new diagnostics and treatments that will enable precision medicine to be successful.

#### RENT AND FACILITIES

Within the budget request, FDA requests a program level increase of \$38.9 million for infrastructure. FDA has a growing workforce of 16,000 full-time equivalents (FTEs), resulting in rising operational rent costs. Without the requested funding, FDA cannot simultaneously support this expanded workforce, critical facility needs, and its increasing programmatic responsibilities. The request also includes funding for a feasibility study to address FDA's expanded workforce and facility needs on the White Oak campus.

#### CURRENT LAW USER FEES

A \$78.5 million increase is requested for current law user fees, which will help FDA fulfill its mission of protecting the public health by assuring the safety and efficacy of human and veterinary drugs, biological products, and medical devices, assuring the safety of our Nation's food supply, and advancing the public health by helping to speed innovations that will offer safer, more effective and higher quality medical products.

#### CONCLUSION

FDA's public-health mission is indispensable to the health and well-being of every American. We carry out our broad public health responsibilities effectively and with relatively few taxpayer dollars, despite dramatic expansions in our responsibilities as a result of new legislation, scientific and technological advances, and a globalized marketplace. Our budget request plans for efficient spending on programs that are essential to providing Americans with the safe foods and safe and effective medical products they expect. We look forward to answering your questions today and to working with you in the coming year.

Senator MORAN. Commissioner, thank you very much. In the hopes that the human trafficking legislation can proceed, we are going to allow Senator Leahy the opportunity first to ask questions so he can get to the Floor.

#### DRUG SAFETY LABELING

Senator LEAHY. Mr. Chairman, I appreciate especially as the newest member of this subcommittee the courtesy of the chairman.

A couple of questions. Commissioner, as I told you privately before, I hate to see you leave. I understand it reaches a point, but thank you for what you have done.

In 2013, FDA issued a proposed rule that ensures generic drug companies can update their safety labels when they learn new safety information. Brand-name manufacturers have that ability now,

and it is tremendously important. I have a constituent, Diana Levine, who was able to seek justice when she got a mislabeled brand-name drug and lost her hand as a result of it.

The FDA's proposed rule for generics has been sitting there for over a year, and the FDA recently reopened its rulemaking which would allow an industry backed alternative that actually turns the existing labeling rules on its head. Their proposal is that no brand-name drug company nor generic drug company could update its label immediately upon learning of adverse side effects, and there would be no liability if something happened.

That does not seem the way it should be. I would hope FDA would commit to complete the rulemaking in a way that if there are problems with a drug, that consumers would know about it immediately, not have it delayed.

Dr. HAMBURG. Thank you for those observations. Certainly, our goal as we are working through this process is to ensure that patients and their healthcare providers can get access to the most recent safety information, wherever it emerges from, whether it is from experience with an innovator drug or generic drug, and that the systems really enable rapid and responsive communication of information.

We have received a lot of comments on the proposed guidelines, lots of different stakeholder perspectives. We have tried to listen very carefully and have held a number of meetings and are holding another public meeting on March 27.

We do plan, of course, to proceed with finalizing, but we want to make sure the process is inclusive, but the goal is to provide the best possible information for patients.

Senator LEAHY. Best possible and the most timely.

Dr. HAMBURG. And the most timely. Realistically, one of the concerns that you may be aware of is if only the innovator can make the change, the sponsor of the original product, then what happens in a world where there is increasing reliance on generics and some of the original innovator drugs are no longer in the marketplace.

Senator LEAHY. Also the warnings can be done immediately, perhaps not the changes immediately, but the warnings could. I will follow up with further questions on that.

#### MAPLE INGREDIENT LABELING

Let me go to what may sound like a parochial thing. In Vermont, winter will end; I have been assured after having lived there for 75 years, it does end. Then we go into maple season. It is very, very hard work on the 30-so gallons of sap for every 1 gallon of maple syrup, but we are able to do this and we can sell it because people rely on it being pure maple syrup.

Here is what is happening. More and more things are being sold. For example, this is pure Vermont maple syrup. I would hasten to add that it is very, very good. We go through a lot at home. Then people have things like this that are sold, maple and brown sugar. You go into the ingredient list, and there is no maple whatsoever. There is caramel color and things like that.

Are you able in your funding to go after people who are actually mislabeling these things, because the people who have done the work for this pure Vermont maple syrup are being badly hurt.

Dr. HAMBURG. Well, certainly the kinds of responsibilities that FDA pursues involves ensuring the accuracy of labeling in key areas.

This issue about the maple syrup is not unknown to us, and in fact, we did recently pursue a criminal case where someone took cane syrup with a little bit of maple syrup flavoring, I guess, and labeled it as a product of Vermont when in fact it was not, and as maple syrup. In fact, those individuals pled guilty. That was back in 2012, I think.

We hope that actions like that send a message, but it is the case that we have such a broad range of responsibilities, we do have to prioritize. Certainly, the issues around being able to pursue all of the misleading and false claims has been one that has been challenging for us in areas that range from food products to drugs to dietary supplements to cosmetics, and it is one where working with industry and working with consumers so we get reports where there are actions that we can aggressively take are very helpful to us.

Senator LEAHY. I realize you have to be selective. I can tell you right now, unless there is really strong action against some of these people, you are going to destroy something that is not only part of the culture of our State, but it is a very important industry in our State, and one in which there are some very, very hard working people who through no part of their own are wiped out.

Dr. HAMBURG. It is very important. The more we can get information about where problems occur, we monitor the marketplaces well. We do inspections to enhance our enforcement activities.

We were pleased we were able to take that action swiftly and aggressively to protect true and authentic maple syrup from Vermont.

Senator LEAHY. Thank you, Mr. Chairman.

Senator MORAN. You are certainly welcome. It is nice to see the Senator from Vermont parochially protecting——

Senator LEAHY. First time a parochial interest has ever come up in my 40 years on this Committee.

Senator MORAN. All the rest of us are certainly reluctant to criticize that circumstance.

#### STATUTORY ROLE OF THE FOOD AND DRUG ADMINISTRATION

Commissioner, let me ask first, one of the areas that I have focused some attention on in my time on the Appropriations Committee, and Senator Blunt is now the chairman of the Labor, Health, and Education Appropriations Subcommittee, but what is the formal statutory as well as informal relationship between the Centers for Disease Control (CDC), the National Institutes of Health (NIH), the Department of Health and Human Services (HHS), how does FDA statutorily and otherwise relate to the healthcare issues, the health issues, associated with those other agencies?

Dr. HAMBURG. We are one of the agencies of the Public Health Service, and we are part of the Department of Health and Human Services. I report to the Secretary of Health and Human Services. Many of the authorities that I have as FDA Commissioner derive through authorities given to the Secretary.

Certainly, we work very closely with our partners in the Public Health Service. There are many issues of overlapping concern, whether it is food safety and the infectious disease work that NIH does, the outbreak investigation work that CDC does, and the product oversight that we do. We work together as a team or in response to an emerging public health crisis like Ebola, where we all have important roles to play in order to support an effective and meaningful public health response.

#### DIETARY GUIDELINES

Senator MORAN. Let me ask about one or two of those arenas. In regard to dietary guidelines, what role will FDA have in advising the Department of Health and Human Services?

Dr. HAMBURG. For the dietary guidelines, at least as I understand it, it is a process that ultimately involves decisionmaking that is coordinated between the Secretary of Health and Human Services and the Secretary of the Department of Agriculture, USDA.

FDA does play a role in reviewing reports and information that goes into the final determinations, and we of course bring our science based approaches to our recommendations in terms of nutrition science and health.

Senator MORAN. What is the status of that process now at the Department of Health and Human Services and your role?

Dr. HAMBURG. I believe there is a report that is currently under review that was developed by a group of outside scientific experts, and we like other components of HHS have been asked to review that report and make comments for the Secretary.

#### EBOLA EMERGENCY APPROPRIATIONS

Senator MORAN. You mentioned Ebola, one that the Centers for Disease Control as well as NIH was actively engaged in. Congress appropriated additional money to the FDA to expedite and develop the availability of medical products related to Ebola.

Can you bring us up to date on the status? What approval process success have we had in the effort to combat Ebola?

Dr. HAMBURG. The FDA has been very actively involved in responding to Ebola. We are not quite as visible. We are not the front page news on the response to the Ebola crisis, but we have played a very meaningful role in terms of both trying to make unapproved medical products available as needed for diagnosis or treatment of individuals at risk for disease or with disease.

Importantly, also working with our scientific colleagues to really put in place the systems for scientific evaluation and research so that we can actually learn what works and what does not in terms of new treatments and vaccines that may have a very important role in this continuing outbreak, but will be absolutely crucial to have when there is a future epidemic.

Sadly, by the nature of this disease, there almost certainly will be future problems with Ebola in Africa, and perhaps in other places.

We also have a role in monitoring for fraudulent products and fraudulent claims. Sadly, in the Ebola situation as we have seen in other public health crises, there are people that readily jumped

to the opportunity to try to sell products that offer hope but no proven value, so we also are taking action against some fraudulent products in the marketplace.

Senator MORAN. Commissioner, can you point to changes in process, in other words, expediting the process to get medical approval accomplished? What has happened since Congress gave the supplemental appropriations to FDA that is different today than it would have otherwise been?

Dr. HAMBURG. Congress has been beneficial in our ability to respond in a number of ways, certainly the supplemental funds that were given for Ebola will make a significant difference. As yet, those funds have not been expended. We have responded pulling from other resources, but those dollars are going to be very meaningful in our overall program.

Authorities that Congress has given us at earlier points have also made a difference. The emergency use authorization (EUA), for example, that was part of the Pandemic and All Hazards Preparedness Act (PAHPA) legislation, has enabled us in this context and in other settings to be able to make as yet unapproved diagnostics available so that better assessments of patients and their needs can be made.

In response to Ebola, we have done a significant number of EUAs, making those products available, and certainly some of the flexibility in terms of regulatory pathways that Congress has given us has enabled us to move more swiftly.

Senator MORAN. Thank you. Let me now turn to the ranking member, Senator Merkley.

#### TOBACCO DEEMING REGULATION

Senator MERKLEY. Thank you very much, Mr. Chair. Thank you for your testimony, Dr. Hamburg. It will not surprise you that I want to start by addressing the rules controlling the regulation of tobacco products.

It was 2009 when the United States, Congress, and the President passed legislation giving FDA the power to regulate these products. We are now in 2015, 6 years later. We do have a draft deeming rule out, and comments have been turned in. At last count, I understand the goal is to have a final deeming rule out by June.

Can you give us assurances that we are going to have this rule by June, 6 years since the legislation was passed?

Dr. HAMBURG. I can tell you that it is my strong commitment and that of the team at the FDA—we are shooting very hard for that June timeframe. We feel this is an absolutely essential regulation that is foundational for many other aspects of our ability to meaningfully regulate tobacco products that are in the marketplace and may be in the marketplace in the future.

I share your deep interest in this and can assure you of the commitment of our agency. We did, as I think you know, get an enormous number of comments on the deeming rule when we did the proposed reg. I think it was more than 135,000. Some of them were duplicative, I will say. Serious comments.

We are systematically going through. We knew we would get a lot of comments. We geared up for that, and we do not feel that will be an impediment to meeting our tentative, and publicly indi-

cated the goal in terms of what was put forward in the unified agenda of June 2015.

Senator MERKLEY. Can you give us some sense as to whether the final rules will prevent the tobacco industry from selling candy-flavored products?

Dr. HAMBURG. You know, I cannot comment on what is in a rule that is still in formulation.

Senator MERKLEY. Do you think it would be a good idea for the final rule to include—

Dr. HAMBURG. Let me say this is an area of intense focus and concern. One of the things that I would like to highlight in terms of FDA activities that I think are really a contribution has to do with the research that we are actually supporting through our tobacco program to better understand some of these issues about the influence of different aspects of tobacco products on behavior and use, initiation and succession, and also looking at subpopulations who may be using tobacco products differently.

We are investing in some very targeted research activities in different key areas, and also a first of its kind major longitudinal study that we are doing in collaboration with NIH that will give us very important insights, and the data for regulatory decision-making that will be so crucial, so that when we make regulations in key areas, they will be based on good strong science that will meet the public health needs and also be able to survive potential litigation, which we know in this arena can often come.

#### E-CIGARETTES

Senator MERKLEY. Thank you for all that work. During this time-frame, these years that have been passing, many, many new products targeted at children have come forward. New technologies have come forward with the E-cigarettes.

We are finding that children are finding easy access to E-cigarettes. Just to give you an example, I know we anticipate the deeming regulations will require minimum age and i.d. restrictions to limit access to children, but a study funded by the National Cancer Institute published at the beginning of this month showed that getting E-cigarettes online by children is quite easy, specifically found that only 5 of 98 attempts by teens to buy E-cigarettes online were blocked by online vendor attempts to verify customer age.

CDC has also reported the rate of teens who reported using E-cigarettes has doubled just between 2011 and 2012. My understanding is that is continuing to grow very rapidly between 2012 and now.

What this means is while this vacuum exists, and I must say when products are labeled after things like flavored gummy bears and double dutch chocolate, so on and so forth, the targeting for children is quite obvious, and certainly it is well understood that addiction to nicotine occurs in your teenage years, that addiction rarely occurs after the age of 21.

It is obvious why this is being done. This has tremendous, huge health implications for our youth. This is why we are expecting FDA to act as if every person in the agency has a child who might be affected by the ulterior effects of nicotine addiction.

It has been a little bit of a sense by many of us here in Congress, and you know the phrase, "While Nero fiddled, Rome burned." While the FDA is fiddling around with trying to get everything perfect, a tremendous number of our children become addicted to products deliberately targeted at them.

It is in your power to act. If there is any way to convey a sense of urgency that just seems to be missing over the last now 6 years on your way out, as you wrap up, it would be so important to the health of this Nation.

Dr. HAMBURG. I can tell you we do have a sense of urgency. We do understand this is a historic opportunity to transform the oversight of these products and to really bring science based public health regulation to bear.

We feel the same sense of urgency you do to get the deeming rule completed because that is the foundation for some of the other important actions that you are talking about. We do feel that while deeming is one key aspect of what we are doing, we also are making enormous strides forward in other key ways, including limiting access of cigarettes and the other products specified in the Family Smoking Prevention and Tobacco Control Act to children, targeting also an educational campaign at youth.

As you know, much of life-long smoking begins in young people. I think sadly you can get addicted to nicotine at any age, but it is certainly the pattern with smoking that if you start smoking young, you are more likely to continue into adulthood with all of the attendant and preventable health consequences.

I can assure you that terrific important work is going to continue to come out of our Center for Tobacco Products. It is a commitment that extends across the whole agency in terms of its priority. We certainly hear your concerns and want to work with you going forward.

Senator MERKLEY. Thank you very much, Doctor.

Senator MORAN. The Senator from Missouri, Senator Blunt.

#### MENU LABELING

Senator BLUNT. Thank you, Chairman. I look forward to working with you and your leadership on this subcommittee. I have been on this subcommittee as you have, since we came to the Senate. I find it a very encouraging subcommittee to be part of. Certainly, Senator Pryor did a great job of leading the subcommittee the last 2 years, and I would hope that you and Senator Merkley have the same positive relationship that Senator Pryor and I had as we sat in the two seats that you are in now.

Commissioner Hamburg, while we have not agreed on everything you have done, I think the country has benefited from the great capacity, energy, and judgment you have brought to this job. I am glad you have been willing to stay as long as you have. I am sure there are lots of other opportunities out there, and you will soon find out just how good they are, and I hope they are good.

One of the things I have often said in your leadership here, one of the great things you have been able to do is be so knowledgeable in so many areas, that when there was something you did not know, you did not hesitate to say I really do not know and I will find out, which only verified the many things that you did know.

Thanks for the work you have done. Good luck in what you will do next.

Senator Moran has already brought up menu labeling, a topic that you and I have spent a lot of time and energy talking about over the last several years. I know it is an assignment that took a lot more time than anybody would have ever imagined.

I am not going to give you time to respond to it today because we could quickly lose the 3 minutes and 29 seconds I have left.

I do have a series of questions for the record that I am hearing and Senator Moran is hearing, others. What is restaurant type food, what is food on display, what is a standard menu item. There are a number of questions and I have about 15 of them here in front of me that we will ask you and your staff to deal with, not only for the benefit of the committee, but for all the people that currently believe without those questions being answered quickly, they cannot comply by the end of this year with what the Department is asking them to comply with.

#### MOBILE MEDICAL APPLICATIONS

Senator BLUNT. In terms of the new technology out there, I think one of the challenges for the Acting Commissioner and then the full-time Commissioner will be how to deal with everything that is happening and Smartphone technology as a shorthand way to discuss the many things that are going to be out there that will be quickly improved and improvable, and more and more affordable, unless we needlessly stand in the way of that.

I think you are leaving a discussion in place that is a helpful one about at what point does FDA need to be involved and at what point does FDA not need to be involved.

I would hope that discussion goes on where we really try to figure out what kinds of things have life threatening impact and what kinds of things are just simply helpful for you and others to know about your daily health that can be monitored quickly in ways that it has not been before. That is certainly something as a member of this subcommittee I continue to be looking at.

#### GENERIC DRUGS

A couple of quick questions. One, on generic drugs, while I think under your leadership, the approval of new drugs has gotten quicker. The approval of generic drugs has gotten slower. I think we are up to the point now where we have gone from 30 months in 2011 to 42 months in 2014.

I want to talk a little about what we can do to make that move from the more expensive drug to the generic drug happen more quickly than it is happening now, or at least as quickly as it used to happen.

Dr. HAMBURG. I am not aware of those numbers you are citing. I will have to go back. As you say, if I do not know, I will say so. In fact, we have been making a major push in the generic drug area. It is true we have had unacceptable backlogs in approval times.

As part of FDASIA and the user fee negotiations, for the first time in that process, we actually worked with the generic drug industry to develop a user fee program so we could get more ade-

quate resources to do the job both in reviewing drug applications and in addressing the backlog.

We have expanded the program. We have made great progress in addressing the backlog. One of the challenges with generic drugs, which as you note are so important in terms of people having access to important medical care, and they now represent a very, very large proportion of spending on prescription drugs, but many of the generic drugs that are used in this country are actually manufactured overseas.

There is also additional complexity in our approval process of the need to do inspections of the facilities before approval, and the additional time and costs of the international component.

The fact that we have now this user fee program in place, which has measurable goals and performance measures that are transparent and monitored by industry and other stakeholders, I think you are going to see enormous progress. I think we have made enormous progress.

We have addressed 72 percent of the existing backlog that was in place at the time that the Prescription Drug User Fee Act (PDUFA) and FDASIA went into effect.

I think you will be pleased by the progress that has been made and will continue to be made.

Senator BLUNT. Just one follow up on that, Mr. Chairman. I am told there are 4,000 applications pending.

Dr. HAMBURG. That was the backlog at the time that FDASIA was——

Senator BLUNT. What do you think the pending number today is?

Dr. HAMBURG. As I said, I understand we have cleared/addressed 72 percent of that backlog.

Senator BLUNT. I assume other people are applying. What has been added to that number?

Dr. HAMBURG. Our commitment in the PDUFA process, the generic drug user fee process, was that by 2017, we would have eliminated all backlog, existing and from incoming.

Senator BLUNT. You believe you will?

Dr. HAMBURG. I do believe that we will.

[The information follows:]

*Answer.* Based on the volume of generic applications received in previous years, the Generic Drug User Fee Act (GDUFA) [program] assumed that the Food and Drug Administration (FDA) would receive approximately 750 original abbreviated new drug applications (ANDAs) per fiscal year. In fact, we received significantly more in the first 2 years of GDUFA: almost a third more applications in fiscal year 2013; and double the expected number in fiscal year 2014.

Approximately 3,300 original ANDAs are currently pending with the agency while 700 are pending with industry.

We are determined to make significant progress in reducing these numbers over the next few years and achieving GDUFA performance goals.

Senator BLUNT. Thank you, Chairman, for letting me follow up.

Senator MORAN. To the Senator from Montana, I do not think I ever served on a committee in the Senate that we have not been together on, and here you are again. I just want you to know that this subcommittee is going to be very actively engaged, and you are going to have plenty of opportunities to spend your time fulfilling the senatorial responsibilities as compared to anything outside of the United States Senate.

## FOOD SAFETY

Senator TESTER. I appreciate that because as you and I both know, you coming from Kansas and myself coming from Montana, and especially the way I look, food is pretty damn important, okay.

We thank you for your leadership, Mr. Chairman, and Ranking Member Merkley.

Just out of curiosity, do you know where you are going to land when you leave?

Dr. HAMBURG. No, I made my decision to step down independent of future opportunities. I am going to rest, relax, regroup, and then decide. I suspect that I will still be involved in many of the kinds of issues that I have dealt with at FDA.

Senator TESTER. We wish you the best. I have a question here that deals with food safety research. The Center for Food Safety and Applied Nutrition is within your purview; correct?

Dr. HAMBURG. Correct.

Senator TESTER. I have a list. I think this came from you guys. It shows about \$4.5 million in risk analysts and evaluation. I would assume you are talking about the budget partially for the Center for Food Safety?

Dr. HAMBURG. Which number are you referring to?

Senator TESTER. I was just wondering how much money, just to cut to the chase, how much money is dedicated towards the Center for Food Safety and Applied Nutrition out of this budget?

Dr. HAMBURG. I am going to look to one of my helpers here.

Senator TESTER. That is perfectly all right.

Dr. HAMBURG. You want the Center for Food Safety and Nutrition?

Senator TESTER. Yes, I want to know how much money they have to work with.

Dr. HAMBURG. \$1.2 billion.

Senator TESTER. \$1.2 billion?

Dr. HAMBURG. You are interested in research specifically?

Senator TESTER. Yes. My understanding is in research, you are doing your research to find out what will kill you and what will keep you healthy.

Dr. HAMBURG. Yes. We cut up the budget in so many different ways.

Senator TESTER. Can you get back to me on that?

Dr. HAMBURG. Yes.

[The information follows:]

*Answer.* \$1.2 billion is the total fiscal year 2015 food safety funding amount. In fiscal year 2016 the total food safety request is \$1.5 billion. Of the total fiscal year 2016 request, \$355 million in budget authority and user fees is for the Center for Food Safety and Applied Nutrition (CFSAN). This is an increase of \$74.5 million over fiscal year 2015 enacted. CFSAN provides services to consumers, domestic and foreign industry and other outside groups regarding field programs; scientific analysis and support; and policy, planning and handling of critical issues related to food and cosmetics.

The \$4.5 million for risk analytics and evaluation in the fiscal year 2016 President's budget request would support the development of new tools for ranking risks, prioritizing program activities across the FDA Foods and Veterinary Medicine Program based on opportunities to reduce risk, and linking risk-based priorities more clearly with budget formulation and execution. These tools, for example, will better inform FDA about which foods, including animal foods, are most vulnerable to

which bacterial contaminants, and where it should invest its research efforts to most effectively identify how to reduce contamination of food.

Senator TESTER. That is a very critical component to the FDA's job. I do not know that you can tell somebody that they can or cannot put an ingredient into food or into cosmetics or into medicine unless you know what it is going to do.

I am curious to know how much that line item is.

Dr. HAMBURG. Can I also add that I am really delighted that we have a new Director for the Center for Food Safety and Nutrition who brings a strong science and research background, Dr. Susan Mayne, who is here somewhere. There she is.

One of my goals before I step down was to make sure that we had the right leadership. That research activity is so essential to what we do.

#### FOOD INSPECTIONS

Senator TESTER. Very important. I want to touch on one thing, if you want to talk parochial, we will talk really parochial. That is how do you train your inspectors that are in the field? Do you hire them and then just send them out or do they go through training on how to interpret the rules that they have to apply to the individuals on the ground?

Dr. HAMBURG. No, they are hired, looking for certain fundamental credentials, and then they are trained, and training, of course, is an ongoing process, and certainly in a world where there is greater specialization, that training is increasingly important.

Senator TESTER. The point I am going to get to is you have a set of rules. Most people in business can read. Then if an inspector comes out and interprets those rules different than what they are, it really ping pongs that—call them “producer” or whatever you might want to call them.

The question is what is done to hold the inspectors accountable? I am all about inspectors doing their job, but I want to make sure they do their job correctly, as the rule applies.

Dr. HAMBURG. Absolutely. The work of the inspectors is then overseen by a management structure, and there are many decision makers before enforcement actions are actually taken. There is considerable oversight of the inspection activities, but one thing—

Senator TESTER. Just a second, and sorry for cutting you off, we only have about 5 minutes. If an inspector comes out and the producer feels that those rules are being interpreted in a way different than what they are printed, what is their recourse?

Say a manufacturer is manufacturing widgets, and the inspector comes out and says no, you cannot do this because the rules say you cannot do it, and you read the rules, and the rules do not say you cannot do it. What is that widget producer's recourse?

Dr. HAMBURG. To engage with us in a discussion. After the inspection is done, there is a report, and that report is gone over with the product sponsor and can be questioned.

Senator TESTER. But the question is how do you notify, how does that producer of those widgets know who to get a hold of? They are dealing with the inspector. There is a conflict of the way the rule was implemented. Is there somebody—are they told of somebody within the agency that if there is a conflict here, you get a hold

of so and so and they can help remedy it? Do you see what I am saying?

Dr. HAMBURG. Yes. There is a system and people do know how to get in touch with us, believe me.

Senator TESTER. The people who are regulated know how to get in touch with you?

Dr. HAMBURG. I think one of our goals over the course of the last few years has been to try to increase transparency and communication to make it easier and to clarify our rules and expectations.

One of the reasons we are asking for money in this budget for FSMA is to be able to train our inspectors to new systems and provide the proper oversight, and—

Senator TESTER. Right. Excuse me for going over time a little bit, Mr. Chairman. One of the reasons I want to give you money is to make sure that those inspectors are trained and make sure there is the kind of outreach that is going on.

What I do not want to do is give you money if that outreach does not happen and if that inspector training does not happen.

My question to you is when it comes to outreach to folks who are on the ground, you need to regulate them, the people you are regulating, how do you do that outreach? You have some additional dollars for outreach in this budget. How do you do that outreach and where is it focused?

Dr. HAMBURG. The outreach, particularly as we have been working on FSMA, has been really very extensive. We do it by working with both the larger organizations that represent the different food producers and farmers, and also doing regional meetings and on farm visits, et cetera.

I think while there is a huge need to continue those efforts and extend them, I think we have laid a groundwork as we have worked on the FSMA rules for what is a real partnership.

We want to extend the work with State and local partners, and that is part of what is in this budget request, to actually give money to counterparts at the State and local level to help do some of that on the ground work.

Senator TESTER. Appreciate it. Thank you, Mr. Chairman. I would just say I want you to be able to do your job, but I also want you to be able to do it in a way that meets the needs of the consumer and meets the needs of the business community out there, too. Thank you very much, and I do appreciate your work very, very much.

Dr. HAMBURG. Thank you.

Senator TESTER. Thank you, Mr. Chairman.

Senator MORAN. Senator Daines. Welcome.

#### DIETARY GUIDELINES

Senator DAINES. Thank you, Mr. Chairman. You are surrounded by Montanans here this morning. You have John Tester, myself, from both corners of Montana.

I spent 12 years working for Procter & Gamble, and I used to work a lot with the FDA. I really appreciate all the work that you do, and I think I have an understanding of the heavy lift that is entailed in your job every day.

Thank you for coming to this subcommittee hearing today. As you know, Montana is a large producer in ag, it is our number one industry, \$5 billion a year. Maintaining a high-quality food supply is of paramount importance for our producers.

In Montana, agriculture plays an important role in the diets of Montanans, for Americans across the country, and even around the world.

The question I had really relates to some of the dietary guidelines, and specifically in the fiscal year 2015 omnibus, there was a congressional directive that expressed concern that the advisory committee was "Showing an interest in incorporating environmental factors into their criteria," and directed the Secretary to include "Only nutrition and dietary information, not extraneous factors" in the final guidelines.

As you know, the scientific report of the 2015 Dietary Guidelines Advisory Committee was just released last month. It included, and I quote, "Environmental approaches are needed to compliment individual based efforts to improve diet and reduce obesity and other diet related diseases."

The question I have is do you think the advisory committee report is compliant with the congressional directive?

Dr. HAMBURG. Well, as I think you probably know, our role in this is not a direct one, but it is advisory to the Secretary of Health and Human Services in terms of reviewing materials, including the report you mentioned, that then become the basis for decision-making by the Secretary of HHS and the Secretary of the Department of Agriculture.

Our role is really to provide feedback in terms of the science of nutrition and health. The broader issues that you were referring to, I think, were reflected in a report that was done by an outside group of scientists, but in terms of what we will be commenting on to the Secretary of Health and Human Services will be on nutrition science and health.

My understanding is at the end of the day, the decisions that are made will really focus on the dietary guidelines that are science based.

Senator DAINES. Doctor, do you believe the environmental issues are within the purview of developing those dietary guidelines?

Dr. HAMBURG. Well, from the FDA's perspective, as I said, that is not something that we are looking at. My understanding is that the Secretary of Agriculture and the Secretary of Health and Human Services understand their role in terms of establishing the dietary guidelines.

#### FOOD SAFETY MODERNIZATION ACT

Senator DAINES. Okay. FSMA was brought up here a minute ago, I would like to talk about that for a moment. You highlighted the fact that the successful implementation of FSMA is essential to improving food safety.

I have been hearing concerns from Montana ranchers and farmers across our State about the President's budget that is proposing to consolidate these food safety programs currently split between the USDA and HHS into a new agency entirely within HHS.

They are concerned that an inevitable result of such a significant consolidation could negatively impact FSMA, and result in inspection delays and some logistical challenges.

Why are you removing the USDA from the food inspection process?

Dr. HAMBURG. You know, I think what was in the President's proposed budget was really laying out the concept of trying to find more integrated ways of addressing a very important problem of food safety. It is fragmented, not just across USDA and FDA, but also many other agencies of Government.

As you probably know, for a long time there have been discussions about should there be a consolidated approach that would really bring together different components and different agencies.

For us, the need to implement FSMA takes a very high priority, and as we implement FSMA, we are trying to do it in coordination with USDA and other important players at the State and Federal level, and we think it is a process that is working very well, even though we are in different agencies or departments with different legal regulatory frameworks for our work.

The on the ground ability to coordinate has been, I think, very successful, and we expect to build on that.

Senator DAINES. One of the concerns I am hearing from the ag community is the loss of expertise by removing the USDA from the food safety process. Do you have concerns? The USDA has some expertise unique to agriculture.

Dr. HAMBURG. Well, I think these two programs have historically worked quite well together, but they do have very different approaches and different legal regulatory frameworks and different targeted commodities in terms of the work that we do, and certainly different areas of expertise.

As I noted, there are other components of Government that also bear on food safety. I think that it makes sense to look at how we can better coordinate, whether that requires creating a new single agency or whether there are more effective ways for coordination is, of course, a debate.

Senator DAINES. Yes, I think our ag folks are concerned about the subject matter expertise the USDA has brought to the ag portion of that, I guess that would be the voice coming from the ag community.

Thank you. I am out of time, Mr. Chairman.

#### MENU LABELING

Senator MORAN. Thank you, Senator. We are going to have another round of questions, Commissioner. Thank you very much.

I want to address menu labeling a bit more. My understanding is that the FDA has announced something they are calling guidance as of this morning in regard to this issue that Senator Blunt raised about the inability of many who may be or are regulated by FDA in menu labeling, their ability to actually know what to do between now and December.

In cursory review of what FDA has said this morning in what they call guidance, it appears to us that it is simply restating things that have already been put before the public and before this subcommittee previously, and that no real benefit, no additional

certainty or knowledge of what behavior needs to occur, what actions need to be taken, could be garnered by reading what you are calling guidance.

Again, I would reiterate this issue about the scope of what you are asking many to do in menu labeling, and the significant costs it will take to comply with those requirements, and yet the uncertainty about if the business expends that money, whether they will really have met the regulations.

Let me ask a couple of questions about individual or sector of the food industry concerns. One that comes to mind, and Kansas is a place, so I can be provincial this morning, Kansas is a place that originates Pizza Huts, pizza delivery.

It is our understanding that the regulations do not allow the regulations to be satisfied by posting caloric values on the Internet despite the fact that is where most people apparently today order a pizza.

In fact, the requirement is that the information be provided on the box that the pizza is delivered in, and that there are—I do not know what the number is—hundreds of different ingredients that you could order for your pizza, and the ability to label the caloric values on that pizza box for that specific pizza is an impracticality.

Are those issues that you are aware of, addressing and understand the need for common sense, if anybody is going to be able to comply with the direction you are going, particularly in this setting in which it is not a restaurant?

Dr. HAMBURG. Well, the restaurant like establishments is clearly the hardest part of this equation. It was hard as we worked through what should be in the proposed rules, and as we went to finalizing, and now as we move towards implementation, and in particular, some of the foods on display as opposed to the more traditional preset menu kinds of situations.

I think first we have to clarify just misinformation. The requirement you just mentioned for calories on the pizza box is not something that I have ever heard of, and I agree, it does not make sense. We have tried to be quite flexible, recognizing these new ways that foods get sold in our country, and the complexities.

We have tried to address that, and a lot of time was spent on pizzas and the fact that you can have different toppings and arranging for ranges of calories and also recognizing that, at certain places, people order it over the Internet and not where there is a posted menu.

Grocery stores is another area that I know Senator Blunt has been concerned about as well. We are working closely with that industry, with the broad FMI that represents many of the supermarkets, but also individual companies, to try to understand what the questions are.

We have not put out guidance but we plan to propose some guidance or put out a framework to address some of these areas that are more confusing, particularly the food on display.

Our goal in doing this is to not disrupt practices or add unnecessary burden. We want to be able to have a smooth and efficient implementation of this and work with the components of industry as needed to make that possible.

To clarify as explicitly as we can where the problems are and what needs to be done is our goal, and we are underway trying to achieve that, but there is more work to be done.

Senator MORAN. My understanding about something called guidance being issued by the FDA today on this topic, is that inaccurate?

Dr. HAMBURG. I am not sure what that would be referring to. It was a plain language summary of the rule for small businesses, so an effort to try to clarify what is in the rule and what is not.

Senator MORAN. More guidance to come, more actual guidance.

Dr. HAMBURG. Yes.

Senator MORAN. The rule does not require the labeling of a box of pizza for the number of calories based upon the ingredients included in the pizza?

Dr. HAMBURG. Not to the best of my knowledge and belief, no.

Senator MORAN. Well, obviously there is uncertainty about the direction that a business must go to comply with the regulations, and what you described to me as your goal is a good thing.

What it brings to my mind is that getting us from this point to the certainty by December seems pretty far stretched to me, and a delay in the final implementation or the final effect of the rule is something you should consider.

Dr. HAMBURG. There clearly is more work to be done. The discussion we have just had, I think, underscores that there is still considerable confusion about what is actually in the rule and need to spell that out more explicitly, addressing the individual concerns of companies and the industry more broadly, and really narrowing in on some of these areas that are just harder to address and more confusing as we go from the issuance of the final rule to the actual implementation.

Senator MORAN. Do you believe that FDA has the discretion whether to include food delivery services, the pizza delivery and the grocery stores, the salad bar at the grocery store—that was a FDA decision to include, not a legislative requirement?

Dr. HAMBURG. I believe the salad bar issue was actually explicitly in the law, but we were asked to look at restaurants and restaurant like establishments, because the fact is that the world we live in no longer revolves around traditional restaurants, but there are many, many settings where you can get prepared food intended for individual consumption at that site or immediately thereafter, and the law did ask us to look at that broader range.

Senator MORAN. Let me now turn to Senator Merkley.

#### IRRIGATION WATER STANDARDS

Senator MERKLEY. Thank you very much. There is a camp song that has a stanza of “I lika pizza, I lika pie, I don’t like onion in my eye.” I will use that as a transition to talk about onions.

We have a lot of onions growing in Oregon, and in the effort to provide guidelines for the Food Safety Modernization Act, part of that is related to the water that is used in irrigation. My onion growers have been very concerned about this. The initial standard was that the water had to meet recreational water standards.

Would it be fair to summarize that is roughly equivalent to whether a lake is safe to swim in? Is that a fair representation of that?

Dr. HAMBURG. Yes.

Senator MERKLEY. It is largely expected that irrigation water for onions would never meet that standard. The water is precious. It is used to irrigate. It is recollected. It is reused. It goes from irrigation ditch to the field, back to the irrigation ditch.

The feedback, there has now been an exemption granted or at least I think this is in the next version of the rule, that if irrigation water has not been put on a crop for 7 days before it is harvested, then they are exempted from having to meet that standard. Is that a fair way to represent it?

Dr. HAMBURG. Well, I think what I can say is that we heard very clearly that some of what was put forward in the original proposed rule would impose a lot of restrictions that would not meaningfully improve public health and safety, and would produce burdens.

We listened to that. We rethought. We looked at what did the data tell us. We did a supplemental to that proposed rulemaking in order to put forward a new model and approach, and we are confident that as these proposed rules move to final, that the concerns that you and the onion growers have had will be addressed.

I would say there have been other areas where we have learned about concerns, have looked at it in terms of what does the data tell us, where is the evidence, what is the impact on health, and we have tried to learn from what we have heard, to accommodate, to try to achieve the least burdensome approach to meaningful rulemaking that will address the goals of FSMA, which is to improve food safety and actually support a vibrant successful food industry.

Senator MERKLEY. Great. I think that is the least burdensome approach, and certainly appropriate. If you look at this often, I hold a town hall in every county every year and I get a lot of feedback. The onion growers have come out to talk about this issue. They have been very concerned.

Here is where they start the conversation, there is not a single known case of *E. coli* contamination linked to an onion bulb product in America. I believe that is correct. Is it, to the best of your knowledge as well?

Dr. HAMBURG. To the best of my knowledge.

Senator MERKLEY. The reason is because of the way these onion bulbs are harvested, whatever *E. coli* might be there dies. The product has a continual drying period before it gets to the grocery store shelf. Outer layers of the onion are peeled.

For all these reasons, that is why it has not occurred. There has been an impact from green onions from Mexico that are harvested in a completely different way.

I think they appreciate very much that they have been heard, and I appreciate very much they have been heard, because having something that creates a substantial burden without having any public safety is the sort of thing that just drives people nuts.

When people complain about regulations, I say well, give me specific examples, and this is a very specific example. I believe it is

anticipated that they are still going to be asked to test their irrigation water every week and report.

I will continue the conversation with the FDA, but if you know in advance the irrigation water is never going to meet that test, and if you know in advance you are going to be exempted from having to meet that test, maybe that is also an unnecessary burden on the industry, and maybe there is another way to approach it that does not require the expense and complexity of testing and reporting, especially when at the end of the process, they are going to be exempted.

Can I just encourage the FDA to continue to take a look at that?

Dr. HAMBURG. Yes. I think that we have tried to make this a process where we can learn from the real world experience, look at the data and the evidence, and look at the impact on public health. That is, I think, the goals we all share, to ensure that we have a safe, high quality food supply, and that we do not overly burden farmers and producers in the process.

Senator MERKLEY. Just to close with this specific question because my time has run out, can you encourage me as you are leaving the FDA to continue to look at whether the testing requirement under this set of circumstances is still overly burdensome?

Dr. HAMBURG. Yes. In the case of the onion growers, there is the issue of being able to demonstrate bacterial die off. When it sits, as you said, baking in the sun. Those are important factors in terms of what would be required.

It is challenging because number one, there are lots and lots of different food commodities and they all have very specialized issues and concerns as we have learned in the process of doing this. I can tell you I have learned a whole lot more about food, farming production, and consumer preferences as well.

This will be a dynamic process also as we learn more and unexpected things happen as well. We do not see when we complete this rulemaking and implementation of FSMA that we are done with food safety forever because we have to continue to bring new, better science and technology to the process, but our process is that new and better science and technology will actually improve and modernize and streamline some of what needs to be done and provide better monitoring and oversight of our Nation's food supply.

Senator MERKLEY. Thank you.

Senator MORAN. The Senator from North Dakota.

#### EXPANDED ACCESS REQUEST

Senator HOEVEN. Thank you, Mr. Chairman. I would like to thank all of you for being here today.

Dr. Hamburg, I would like to address my question to you. As you are aware, we have a family in North Dakota that is struggling with pantothenate kinase-associated neurodegeneration (PKAN). They have youngsters in the family that are struggling with PKAN. They made a compassionate use application to FDA for use of the drug, RE024. You and I have spoken about this before. The family continues to try to gain compassionate use access to this drug.

I am wondering what you can tell me in terms of helping make that happen.

Dr. HAMBURG. You know, I have not received an update on the status of that. I know you and I have talked, and certainly I can go back and look at the specifics of that instance.

As you know, in terms of requests for expanded access, when requests come to us, we generally, I think 99 percent of the time, actually support the applications of the healthcare provider working with families.

There were some specific issues in this case, the fact that we generally are very supportive, and in this case, there were some concerns. I cannot really speak to the status or the specifics.

Senator HOEVEN. As of our last meeting, at least one of the issues was FDA wanting the manufacturer to do some additional work, make an additional investment in some of the research on the drug, and we were asking if you would work with the company to do that, and also we were appealing to the company directly to do it as well, so they could reach an agreement with you in order to allow the compassionate use for the family.

I would ask that you check on that.

Dr. HAMBURG. I do remember that discussion and we needed the company's permission to be able to share more information with the family and healthcare provider, and with you.

Senator HOEVEN. Right.

Dr. HAMBURG. I do not know—I know our lawyers spoke with the company. Perhaps the company decided that they did not want that information shared. I will go back and learn more.

Senator HOEVEN. I would ask that you update us on that status and anything else you can do. Would you be willing to do that?

Dr. HAMBURG. I would be.

[The information follows:]

*Answer.* I will be happy to follow up with you in a letter, so as to avoid disclosure and privacy issues.

#### RIGHT TO TRY LAWS

Senator HOEVEN. The second thing is in our State, our legislative session is underway. They are considering passing a "right to try" law. I think you are familiar with "right to try" laws that a number of States have now passed, which would perhaps afford an opportunity for this family to go directly to the manufacturer under a contractual arrangement and gain access to the drug.

I just want your reaction to how you would handle that if in fact North Dakota is able to pass that "right to try" legislation, and then how would you approach that, how would you be able to facilitate that option for the family?

Dr. HAMBURG. Well, we do feel that we play a valuable role in the process. At the end of the day, it is the company that has to make the decision to make the product available through an expanded access process.

In many instances, I can tell you that the FDA has played a very constructive role in encouraging the company to in fact make the decision to do so, and in some instances, we may have additional information that can help inform the decisionmaking about whether this is the right action to be taken.

We feel that we play an important role in the system that enables patients to get access to unapproved drugs outside of a clin-

ical trial process when they have a serious or life-threatening condition, but we know many States have been looking at the notion of expanded access, and I do not know the specifics of what is happening in your State.

From my perspective, I would say that the FDA actually is an important partner and makes many contributions to what ultimately will serve the patient best.

Senator HOEVEN. If the State proceeds with the “right to try” law, you would be willing to help with that process?

Dr. HAMBURG. As I said, I do not know anything about the specifics in your State. We certainly would be happy to provide technical assistance or input on aspects, but what I wanted to really emphasize is that we do believe that if you look at experience, FDA is not the barrier to access in the vast, vast majority of cases, and that in fact we do play a valuable role and can provide important information, and often support and almost a form of advocacy for the expanded access program.

Senator HOEVEN. I am asking for your help on both of those options. You are willing to do that?

Dr. HAMBURG. Yes.

Senator HOEVEN. You are willing to provide help for both of those options if we can make one of them work? That is what I am asking.

Dr. HAMBURG. I am willing to work with you to try to better clarify the expanded access program to provide expert input in terms of what might be under consideration, and certainly FDA is very eager to be helpful in expanded access cases.

We actually just recently re-did the paperwork for expanded access requests to come to us, and it was actually described in one newspaper article as a “breathtaking effort to diminish bureaucratic red tape.”

We have been very hard to make this program clearer and more accessible and to help get patients and their healthcare providers access when it is appropriate.

Senator HOEVEN. Thank you.

Senator MORAN. Just a couple more questions, Commissioner. We will do one more round, although I will submit most of my questions for you to answer for the record.

#### MOBILE MEDICAL APPLICATIONS

Senator MORAN. Let me just ask quickly about digital health devices. The FDA has issued guidance that it does not intend to enforce compliance with the standard regulatory controls for medical devices. Let me make sure that my premise is true, unlike my last question. That is true?

Dr. HAMBURG. We have stated, I think, very clearly and put forth a number of documents and reports indicating that we want to take a risk-based approach. We have no need to be involved in the regulatory oversight of the full range of mobile medical apps that are coming into the marketplace, many of which can provide a great deal of important information to individuals about their health status.

We really want to focus on the mobile medical apps where there is a very important diagnostic or medical device activity that really

bears on medical decisions, medical interventions, and can have serious implications for health.

It is not the platform, but it is the function, and we want to focus on the high risk.

Senator MORAN. Is there any more certainty that can be provided so that we do not stifle innovation in this arena? Can FDA make more clear what can be created, what can be innovated, without the threat of the regulatory burden?

Dr. HAMBURG. I think as you know this is sort of an area of a great deal of new activity really exploding in many ways, and a lot of companies that previously had not been working with the FDA in terms of regulatory oversight as well.

We are trying very hard in a timely way to put out information in terms of our regulatory role and how we will undertake the oversight of these mobile medical apps.

In addition, we have had a lot of public meetings, and will continue to do that, meetings with individual companies and stakeholders. I think it is going to be an ongoing process because there are misperceptions. People are very worried that we are going to be regulating products that we have no intention of providing that kind of regulatory oversight.

We do want to focus on those higher risk products where important medical decisions may be made, and if it does not work, it is going to put the patient at risk, and if it was an EKG device in your doctor's office, it would be regulated by the FDA, and you would want it to be accurate so you would not have the wrong treatment. If it is an iPhone that is doing the same thing, you still want it to be accurate.

I think there are a lot of good examples where it really matters. There are a lot of examples where we do not feel a need to step in and provide regulatory oversight because the implications of the procedure being undertaken, the function of that mobile medical app does not carry with it the same risks for patients and does not form the basis for the same kind of medical decisionmaking and action.

#### FOOD SAFETY MODERNIZATION ACT RULES

Senator MORAN. Will FDA be able to meet the court-ordered deadline on FSMA and its regulations?

Dr. HAMBURG. We are committed to that; yes.

Senator MORAN. Will the FDA be able to meet its deadline as ordered?

Dr. HAMBURG. Yes. This is something that is just enormously important, and we have been working very hard. The process took a little bit longer than we hoped in part because of the level of outreach that we have done, and we felt the responsibility to go back with the supplementals to get more feedback and clarify some of the areas that had been raised as concerns.

Yes, we are on track to meet those goals, and we have been working closely with all of the components of the system that have to be part of that in terms of HHS and the White House review. We are all committed and determined to be successful.

Senator MORAN. Your budget, the administration's budget proposes substantial funding increases to modernize the food inspec-

tion system. We talked a little bit about that in other questions. Yet, this is considered transformational. FSMA is considered transformational.

If it is transformational, is there something that we will spend less money on because we are doing things in a new way? If it is transformational, it seems to me it ought not always be that we need more money to transform. It ought to be we are spending less money over here doing things better and transforming to a better system that costs less.

Dr. HAMBURG. I think FSMA will be transformational in the sense of saving money and saving lives. We are shifting from a system that was reactive, waiting for problems to occur, and then trying to fix them after the fact, to one that will be preventive.

It means we will prevent foodborne outbreaks. One in six Americans get ill from foodborne illness every year. There are \$78 billion worth of preventable costs to the healthcare system because of foodborne illness, 3,000 deaths a year as well.

The cost to industry, every time there is a recall, even if it is not your product, if it relates to your product, like there was a spinach and *E. coli* outbreak in California a number of years ago, it was one company, but the whole spinach industry was affected, and not just affected during the period of concern about the outbreak, but I am told it took years. It may not have even occurred that spinach purchasing went back up to the pre-outbreak levels.

To be able to have a preventive approach, to be able to really enhance trust and confidence in the food supply, to prevent illness, to enhance the ability of industry to be able to excel in terms of food safety, the confidence of buyers and consumers in this country, and frankly, for trade and exports, all of that are going to be benefits of FSMA.

We certainly appreciate what Congress did in giving us these new responsibilities and authorities, and I think it is going to make a lasting difference to the benefit of all.

Senator MORAN. Thank you.

Senator Merkley.

#### FOOD SAFETY MODERNIZATION

Senator MERKLEY. Thank you very much. I know it takes a lot of work to address the seven different categories and rules that are coming out in FSMA. There is a lot going on there in each one of those rules.

I appreciate the enormous work that has gone in to realizing this vision for food safety.

Back in 2009, there was a *Salmonella* outbreak in peanut butter, and 700 people became significantly ill, nine people died. Someone who almost died was a little 3-year-old boy named Jacob Hurley. This compelled his father, Peter, to become a major advocate of trying to tackle this challenge. I have had a number of conversations with Peter and his family in the course of the time we were considering this act.

Now we are down the road to having this, as you put it, preventive approach rather than the reactive approach, which is exactly the right framing.

What can I tell Peter and Jacob today about what will happen, using peanut butter as an example, making it much less likely for peanut butter to have a contamination that could cause an illness?

Dr. HAMBURG. Well, I think you can say that advocacy work has made a difference because FSMA was passed and it is now being implemented. We do need these additional resources now to actually go from what is being spelled out in a set of, I think, very thoughtful and responsible regs that have been developed, and actually seeing the difference on the ground.

We need the money to make that happen, and I do not think while our budget authority request is bigger than you have seen before, that it is excessive in terms of what is needed.

You may be aware at the time the law was passed, the Congressional Budget Office (CBO) estimated that it would take about \$580 million over 5 years to implement FSMA appropriately. If we get the \$109 million, we will be about halfway to what they thought we needed. We are trying to implement as efficiently as possible.

We need to do a number of things. We need to modernize our inspections with training and education to reflect the needs of a preventive approach. We need to work with industry to really make sure they understand what is expected of us, the discussion I was having with Senator Tester and some of the others about the importance of the open communication and understanding and technical assistance.

We need to work with our counterparts at the State level, and actually a significant amount of our ask, I think it is \$32 million, will be going to the States because they need to be working on the ground level to make sure this new approach is in place and working.

We have to also address the international component, which is enormous and growing in terms of the foods that are coming in from other countries and countries with much less stringent oversight in terms of safety and quality, so we need to get the resources to implement the foreign supplier verification process, to be able to ensure an adequate number of foreign inspections, and to really make sure that both for consumer protection and to have a level playing field for domestic producers that the same standards and quality approach—

Senator MERKLEY. I might just interrupt you here so I can follow up a little bit before I run out of time. Would it be appropriate for me to characterize it this way, going back to the peanut butter example, the way the ingredients are grown, the way they are harvested, the way they are processed, additional testing along the way, we are changing the systems, we are enhancing the testing all to create a system where the potential for contamination is absolutely minimized.

Dr. HAMBURG. Where the potential for contamination will be minimized and any problems we identify as swiftly as possible are addressed.

Senator MERKLEY. Thank you.

Senator MORAN. Senator Merkley, thank you very much. Commissioner, thank you very much. Doctor, we wish you well. Thank

you for your testimony. Thank you for your team's presence with us this morning.

#### ADDITIONAL COMMITTEE QUESTIONS

For members of the subcommittee, any questions that you would like to submit for the record, and I will have several myself, should be turned in to subcommittee staff within 1 week, which is Thursday, March 19, and we would appreciate if the FDA could respond to those questions within 4 weeks from that.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

#### QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

*Question.* Where is the FDA in the process of approving the backlogged applications for new sunscreen products?

*Answer.* As required by the Sunscreen Innovation Act (SIA), FDA has completed several important steps in the review process for sunscreen active ingredient applications marketed for a material time and extent in other countries and determined eligible for review prior to enactment of the SIA. We have reviewed all eight pending sunscreen active ingredient applications, evaluated submitted data, and identified the missing information we need to determine that sunscreens containing each ingredient would be generally recognized as safe and effective. We have issued proposed orders outlining additional data needed in order to make a determination that each ingredient meets this standard.

As outlined in the SIA, the data requested must be gathered and submitted to the FDA for evaluation before the agency can proceed to a final sunscreen order. We look forward to receiving and reviewing the data. The agency is committed to doing its best to continue to meet future deadlines under the SIA—and to provide American consumers with additional options for safe and effective sunscreen ingredients.

*Question.* Shouldn't more focus and priority be placed on preventive care for skin cancer? Why are Americans having to wait so long for new sunscreen products?

*Answer.* Americans currently have access to numerous sunscreen products. These include broad-spectrum products with an SPF value of 15 or higher, which, if used as directed with other sun protection measures, decrease the risk of skin cancer and premature skin aging caused by the sun. As described in the preceding response, FDA is actively working to assure that sunscreens, including sunscreens that would contain the ingredients being evaluated under the SIA, provide safe and effective protection.

Heightened concerns about the risk of skin cancer and premature aging have fundamentally altered consumers' use of sunscreen products over the past few decades. Americans once applied the products in modest amounts while at the beach or exercising during peak hours of summer sun exposure. In contrast today, Americans— young and old, fair-skinned and not—now routinely spread on sunscreens all year round. A large increase in the amount and frequency of sunscreen exposure combined with advances in scientific understanding that some sunscreen ingredients may be absorbed into the bloodstream have raised safety concerns. Commercial marketing experience alone is inadequate to evaluate these concerns.

The SIA does not relax the FDA's scientific standards for evaluating safety and effectiveness or the requirement that the agency have adequate data on which to base a generally recognized as safe and effective (GRAS/E) determination. FDA has proposed data requirements, unanimously supported by an Advisory Committee panel of independent scientific experts, to meet this standard. We look forward to receiving and reviewing industry data—and helping American consumers make informed decisions about these products.

*Question.* The agency's tentative determination on partially hydrogenated oils represents a substantial shift from the current framework. Why did the FDA not undergo the customary rulemaking process and instead issue a determination?

*Answer.* Our action conforms to FDA regulations which set forth a process by which the agency, on its own initiative or in response to a petition from an interested person, may determine that a substance is not GRAS. Specifically, title 21 of the CFR, section 170.38(b)(1), provides that FDA may initiate this process by issuing a notice in the Federal Register proposing to determine that a substance is

not GRAS and is a food additive subject to section 409 of the FD&C Act. Section 170.38(b)(2) requires the notice to include a period of 60 days for comment.

*Question.* If the health concern is over trans fat, why focus on PHOs and not trans fat specifically?

*Answer.* Partially hydrogenated oils (PHOs) are ingredients added to food to achieve specific technical effects, and are the primary dietary source of artificial trans fat in the United States.

*Question.* Given that PHOs are used globally, the agency's determination could potentially impact trade compliance. Did the FDA consult Federal agencies with trade oversight before issuing this determination?

*Answer.* FDA is charged with protecting the U.S. food supply, and applies its regulatory authorities to ensure that food, including all substances added to food, is safe. We believe our tentative determination complies with all relevant legal requirements. We further note that a number of other countries have already placed restrictions on the use of trans fat-containing ingredients, including Denmark, Austria, Hungary, and Switzerland. In addition, the European Commission is currently considering action on industrially produced trans fat in food.

*Question.* This past December, Congress enacted legislation that gives the FDA authority to expediently add diseases to the Tropical Disease Priority Review Voucher Program to spur development of vaccinations for neglected diseases. Are you considering adding diseases to the program, and has FDA begun the work to make the additions?

*Answer.* FDA is considering adding diseases to the list of tropical diseases in the Priority Review Voucher program. The legislation enacted last year expanded the voucher program to Ebola and streamlined the process for the agency to add other qualifying diseases, if it determines such additions are appropriate. We are working on these issues now.

*Question.* Is Chagas disease under consideration?

*Answer.* Yes, FDA is considering adding Chagas to the list of tropical diseases. Adding Chagas to the list was recommended by members of Congress and stakeholders attending a public meeting on tropical diseases that qualify for tropical disease vouchers.

*Question.* How long will it take FDA to complete the process to add a new disease?

*Answer.* While FDA cannot specify a particular timeframe for the designation process, the agency will follow this new, expedited process to make any changes as quickly as possible.

*Question.* FDASIA was enacted by Congress 3 years ago and required FDA to issue new regulations for medical gases. Not only has there been no proposed rule, Congress has yet to receive the report that was due over a year ago. What is the status of the agency issuing these regulations?

*Answer.* FDASIA requires FDA to:

- Review current regulations regarding medical gases, obtain input from medical gas manufacturers and other interested parties, and determine if any changes are necessary.
- Provide a report to the Senate Committee on Health, Education, Labor and Pensions and the House Committee on Energy and Commerce on its findings.
- If changes are determined to be necessary, finalize such changes by July 2016.

As you note, the report to Congress is past due. We apologize for the delay and are working to complete and submit the report as soon as possible. We have sought and received comments from medical gas manufacturers and other interested stakeholders, and we have conducted an extensive review of the Federal drug regulations with regard to medical gases. We held a public meeting on this topic in December 2013. In addition, Dr. Janet Woodcock, the Director of FDA's Center for Drug Evaluation and Research, met with representatives of the medical gas industry in February 2014. Following this meeting, the Compressed Gas Association and the Gas and Welding Distributors Association submitted a joint revised set of proposed regulatory changes for FDA's consideration. We have completed our review of these proposed changes and are working to finalize and submit the Report to Congress.

*Question.* Will the FDA have the final regulations in place by the January 9, 2016, deadline?

*Answer.* FDASIA does not require regulation changes unless they are deemed necessary as a result of the regulation review. If changes are deemed necessary, section 1112 of FDASIA requires final regulations by July 9, 2016, 48 months after enactment of the act. We will do our best to meet the deadline.

*Question.* As you know, CFSAN has for a number of years supported several Food Safety Centers of Excellence that help to support the food safety research needs of the FDA through basic research and various other tasks. The Committee has long been supportive of the work of these Centers. Can you please provide some back-

ground on Food Safety Center of Excellence funding for fiscal year 2015 and fiscal year 2016, and whether or not you can provide an increase in basic research support levels in fiscal year 2016?

*Answer.* The FDA Food Safety Centers of Excellence (COEs) support critical collaboration between FDA and academic institutions to advance regulatory science through innovative research, education, and scientific exchanges.

In fiscal year 2014 CFSAN awarded \$11.025 million in funding to the COEs. While FDA intends to maintain strong support for these Centers, final decisions on precise funding amounts for fiscal years 2015 and 2016 are still pending.

*Question.* It is my understanding that the FDA requested authority from the Office of Management and Budget to conduct a study on the proposed changes to the Nutrition Facts Panel (NFP) related to consumer comprehension of an “added sugars” disclosure on the NFP in addition to “sugars.” Additionally, FDA published in the Federal Register on March 3, 2014, its plan to conduct a consumer study to better understand “how consumers would comprehend and use this new information.” Can you please provide me with the status of this study, the data produced to date, including the questions and responses specific to the declaration of added sugars on the Nutrition Facts label, and the FDA’s plans and timing for making these results available to the public for comment?

*Answer.* FDA has completed the study of consumer comprehension of an “added sugars” disclosure on the NFP in addition to “sugars.” We are in the process of preparing a report summarizing the data from this study. We will make the report available to you and the public when it is complete.

*Question.* About a month ago, the New York State Attorney General claimed that GNC and three other retailers were selling herbal products that did not contain the labeled ingredients. This caused and continues to cause quite a stir inasmuch as half of all Americans take supplements. The New York Attorney General’s allegations were based on a series of tests known as DNA barcoding. DNA barcoding, I am told, is an inappropriate test for herbal extracts because the extraction process tends to destroy the DNA markers. I am also told that the U.S. Pharmacopeia and the FDA do not use this type of test to determine whether or not certain herbal extracts are present in a product. Can you confirm that, in fact, the FDA agrees that DNA barcoding is not an appropriate test for herbal extracts?

*Answer.* Speaking generically, FDA does not use DNA sequencing for botanical authentication. The FDA’s current research and development for DNA sequencing based methods for plants is focused on the development of a plant species DNA library and development of validated methods for identification of botanical materials.

We are not privy to the details of methods employed during the NY Attorney General’s investigation and, because of this, FDA has not stated whether DNA barcode testing is an appropriate test or examination for this investigation. Currently, if FDA were to use DNA methods on herbal extracts, we would use them in combination with established chemical or other acceptable methods historically used to verify the identity of these products. At this time, FDA does not use DNA sequencing by itself to analyze an herbal extract.

---

#### QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

##### BIOSIMILARS

*Question.* I want to state up front that I support the development and marketing of biosimilars. That is why I have been incredibly frustrated at the lack of transparency in the implementation process. The first approval should have been well understood and considered a real accomplishment. Instead, it has highlighted that all the policy and implementation questions we have been asking you to answer remain unanswered due to the lack of published guidance.

Commissioner Hamburg, you stated at a hearing just last week before the House Appropriations Subcommittee that guidance on naming was coming soon. Two days after that hearing FDA approved the first biosimilar product, but we still don’t have any guidance. Can you please share your exact timeline for publishing guidance?

*Answer.* While the agency cannot provide a specific timeline for the release of any guidance, FDA continues to clarify our approach to implementation of the Biologics Price Competition and Innovation (BPCI) Act and provide guidance and information to assist biological product developers—sponsors/companies—with bringing biosimilar and interchangeable products to market.

FDA has recently issued three final guidances:

—Scientific Considerations in Demonstrating Biosimilarity to a Reference Product

- Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product
  - Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009
- FDA has published the following draft guidances since 2012:
- Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product
  - Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act
  - Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants
  - Biosimilars: Additional Questions and Answers Regarding Implementation of the BPCI Act of 2009

The agency is continuing to review the comments received as we move forward in finalizing these draft guidances. In addition, FDA expects to issue draft guidance in 2015 on the following topics identified in CDER's Guidance Agenda:

- Considerations in Demonstrating Interchangeability to a Reference Product
- Statistical Approaches to Evaluation of Analytical Similarity Data to Support a Demonstration of Biosimilarity
- Labeling for Biosimilar Biological Products
- Nonproprietary Naming for Biological Products

*Question.* Will the guidance document on naming address the confusion raised about labeling of biosimilars? Specifically, the label for the biosimilar product FDA approved on March 6 appears to contradict the agency's current draft labeling guidance. Does FDA still believe that health professionals should have a label that includes all the information necessary to make prescribing decisions, including a statement that a product is a biosimilar and whether a product has been determined to be interchangeable? The label for the product you just approved does neither.

*Answer.* FDA believes that healthcare professionals should have product labeling that includes the essential scientific information necessary to make informed prescribing decisions for their patients. FDA expects to issue draft guidance on labeling for biosimilar products in 2015. The public will be provided with an opportunity to comment on this draft guidance when it is published.

*Question.* Further, given the lack of clarity on the question of extrapolation in the product's label, when exactly is the guidance on that topic expected? How will physicians know which indications were actually researched and validated for the biosimilar?

*Answer.* FDA undertakes a rigorous and thorough evaluation to ensure that a biosimilar product meets the statutory and regulatory standards for approval and has been determined to be safe and effective under the conditions of use described in approved product labeling. Approval of a biosimilar product is based on review of evidence that may include structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamics data, clinical immunogenicity data, and other clinical safety and effectiveness data that demonstrates that the product is highly similar to the reference product (notwithstanding minor differences in clinically inactive components) and that there are no clinically meaningful differences between the biosimilar product and the reference product in terms of safety, purity, and potency.

Additionally, a biosimilar application must include information demonstrating, among other things, that the proposed biosimilar has the same route(s) of administration, dosage form(s) and strength(s) as the reference product, and that the condition(s) of use for the proposed biosimilar have been previously approved for the reference product. To determine which indications have been approved for a biosimilar product, healthcare professionals are advised to review the labeling—prescribing information—of the biosimilar product.

FDA has issued final guidances, "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," and "Biosimilars: Questions and Answers [Q&A] Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009" (Q&A I.11), describing the potential for a biosimilar applicant to extrapolate data derived from a clinical study sufficient to demonstrate safety, purity, and potency in an appropriate condition of use to one or more additional conditions of use for which licensure is requested and for which the reference product is licensed, if sufficient scientific justification is provided. FDA expects to issue draft guidance on labeling for biosimilar products in 2015. The public will be provided with an opportunity to comment on this draft guidance when it is published.

*Question.* How does FDA intend to update the label for the product with respect to the name? I understand that it was approved with a “placeholder” for the name. What does this mean and why did FDA proceed this way?

*Answer.* The agency had an application for a biosimilar product that was ready for approval and designated a proper name with a distinguishing suffix for this product (filgrastim-sndz) on a product-specific basis while continuing to consider broader policy issues regarding the nonproprietary names of biological products. Some Agency communications used the term “placeholder” to describe this non-proprietary name. That term was intended to indicate that FDA’s designation of a nonproprietary name for this product should not be viewed as reflective of the agency’s decision on a comprehensive naming policy for biosimilar and other biological products. FDA intends to issue draft guidance on how current and future biological products marketed in the United States should be named in the near future. If the filgrastim-sndz name is inconsistent with the naming policy FDA adopts for biological products, however, FDA would work with the applicant to minimize the impact that labeling changes would have on the manufacture and distribution of this product.

#### UNTITLED LETTERS

*Question.* I understand that the FDA uses untitled letters to increase public accountability of firms, which may deter future violations and increase compliance with the law. However, it has come to my attention that the Center for Biologics Evaluation and Research (CBER) may be systematically using untitled letters as a means to reclassify tissue products instead of following protocol established in the Administrative Procedure Act.

Prior to issuing each of the untitled letters, does FDA issue guidance or regulations which provided clarity regarding the classification of the product(s)? If so, please provide the key citations.

*Answer.* CBER does not systematically use untitled letters as a means to reclassify tissue products instead of following the regulations that have been established under the Administrative Procedures Act.

The requirements for FDA’s regulation of human cells, tissues, and cellular and tissue-based products—HCT/Ps—are found in 21 CFR part 1271. Subpart A contains general provisions, including the criteria that must be met in order for an HCT/P to be regulated solely under section 361 of the Public Health Service Act (PHS Act) (21 CFR 1271.10). In accordance with 21 CFR 1271.20, if an HCT/P does not meet the criteria under 21 CFR 1271.10, it will be regulated as a drug, device, and/or biological product under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and/or section 351 of the PHS Act. These regulations were finalized after a period of public notice and comment, consistent with the Administrative Procedures Act.

As required by law, FDA publishes regulations in the Federal Register. FDA usually uses “notice and comment rulemaking” to issue regulations. The first public step in the notice and comment rulemaking process is for FDA to issue a proposed rule, which explains what we intend to require, and asks for public comment. Based on the comments, FDA will then decide to end the rulemaking process, issue another proposed rule, or issue a final rule. The final rule preamble responds to comments on the proposed rule and explains the new regulatory requirements.

FDA issues guidance documents, which describe the agency’s interpretation of or policy on a specific regulatory issue. They do this by providing recommendations for meeting the criteria or requirements in regulations. 21 CFR 10.115(b). Guidance documents may relate to the processing, content, and evaluation of submissions as well as inspection and enforcement policies. In the context of HCT/Ps, it is anticipated that guidance documents will improve stakeholders’ understanding of the definitions in part 1271.3 and how to apply the regulatory criterion in 21 CFR 1271.10.

An untitled letter is an advisory action that cites violations that do not meet the threshold “regulatory significance for a warning letter. The format and content of an untitled letter should clearly distinguish it from a warning letter. For example, as discussed in the FDA’s Regulatory Procedures Manual, untitled letters are not titled; do not include a warning statement that failure to take prompt correction may result in enforcement action; do not evoke a mandated district follow-up; and request (rather than require) a written response from the firm within a reasonable amount of time. They are issued to address inspectional findings or compliance issues at a specific firm.

Here is a link to FDA’s Regulatory Procedures Manual for the record: <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176871.htm>.

*Question.* Do you currently have any policies and procedures related to how soon after you issue an untitled letter to a company you subsequently post it on your Web site? If not, are you considering such a policy?

*Answer.* CBER's policy is to post all untitled letters on its Web site as soon as practicable after confirmation of receipt by recipient and a review of the letter prior to disclosure to include redaction of any trade secrets or confidential commercial information. CBER started posting these letters in 2002; this complies with the commitment made by the agency in the Transparency Initiative.

*Question.* Do you currently have any policies or procedures related to the issuance of an untitled letter related to the appearance of the letter? For instance, do you require that all untitled letters issued to a company have the header "Untitled Letter?"

*Answer.* As described in the FDA's Regulatory Procedures Manual, chapter 4-2, untitled letters are not titled, and therefore do not have the header "Untitled Letter" on the letter. Here is the link to FDA's Regulatory Procedures Manual for the Record: <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176871.htm>.

*Question.* For the untitled letters in question, were any issued to the company without the header "Untitled Letter"? If so, when the letter was subsequently posted on your Web site, did it include such a header?

*Answer.* Untitled letters are not titled, and therefore do not include the header, "Untitled Letter." For clarity, and to distinguish them from warning letters, untitled letters are identified as such on CBER's Web site.

*Question.* Prior to issuing each of the untitled letters, did you have any communications (formally or informally) with the company regarding the issue that was the subject of the untitled letter?

*Answer.* If the untitled letter was issued subsequent to an establishment inspection, the FDA investigator may have informally discussed the situation, although they are not required to do so. An untitled letter can often be the initial communication with regulated industry concerning regulatory violations.

*Question.* Prior to issuing each of the untitled letters, did you use alternative regulatory options to resolve questions related to product classification, which may include formal inquiries (whether via official correspondence or via telephone) or directed inspections with appropriately qualified inspectors?

*Answer.* In determining whether to issue an untitled letter, FDA officials generally consider whether evidence shows that a firm, product, and/or individual is in violation of the law or regulations. Such evidence may have been obtained during a routine or directed inspection, or other means of surveillance, such as Internet Web site surveillance. Untitled letters are often used as an initial correspondence and can be an alternative to other regulatory options, such as a warning letter.

Regarding jurisdictional questions, FDA's Tissue Reference Group—also known as the TRG—was created as specified in the "Proposed Approach to the Regulation of Cellular and Tissue-based Products" published by FDA in February 1997. The purpose of the TRG is to provide a single reference point for product specific questions received by FDA—either through the Centers, or from the Office of Combination Products (OCP)—concerning jurisdiction and applicable regulation of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps). FDA has publically posted information on how manufacturers can submit inquiries to the TRG, as well as publically disclosing TRG recommendations regarding HCT/P classification, on its Web site.

Here is a link to FDA's Tissue Reference Group's Web site: <http://www.fda.gov/biologicsbloodvaccines/tissuetissueproducts/regulationoftissues/ucm152857.htm>.

OCP issues classification and jurisdiction assignments for medical products. Classification and jurisdiction assignments can be made informally or formally. Informal assignment requests should be made by directly contacting OCP. Formal assignment requests can be made by submission of a Request for Designation Document, also known as RFD, to OCP.

Here are links to the Office of Combination Products' Jurisdictional and RFD Information: <http://www.fda.gov/CombinationProducts/JurisdictionalInformation/default.htm> and <http://www.fda.gov/CombinationProducts/RFDProcess/default.htm>.

*Question.* Subsequent to receiving an untitled letter, did any company request that you post a response to such letter? If so, did you post the response to the letter?

*Answer.* FDA policies and procedures do not currently include the posting on the Internet of manufacturers' responses to FDA's untitled letters. CBER has only rarely received a request to post the response to an untitled letter and declined to do so. However, a company is always able to post information on its own Web site, including its response to the untitled letter and any other information in regards to addressing FDA's concerns.

*Question.* Have you considered issuing formal “close out” letters, similar to what is done for warning letters?

*Answer.* FDA policies and procedures do not currently call for issuing untitled letter close-out letters.

#### FDA FOOD SAFETY ACTIVITIES

*Question.* I have heard from many organizations that are requesting appropriate funding for FDA’s food safety activities in fiscal year 2016 and continue to oppose the proposed industry user fees, which have been repeatedly rejected by Congress, to pay for food safety activities. Commissioner Hamburg, do you still believe the user fees are necessary and do the user fees have industry and political support?

*Answer.* In fiscal year 2016, FDA has requested an increase of \$301.2 million to support its FSMA implementation efforts. The request includes a net increase of \$109.5 million in Budget Authority and \$191.8 million in User Fees. The total request is critical to ensure full implementation of FSMA. FDA continues to work with its stakeholders to build support for the proposed food safety User Fees. However, FDA is most concerned with having an appropriate level of funding for successful implementation, not the funding source.

---

#### QUESTIONS SUBMITTED BY SENATOR MITCH MCCONNELL

*Question.* I submitted five questions for the record last year, but never received a response from your agency on a single question. Why has nearly a year gone by without a response from your agency?

*Answer.* FDA did not receive questions for the record from Appropriations subcommittee staff last year. While we were not aware of your questions, we are happy to answer them this year or in a briefing or letter.

*Question.* Prescription drug abuse remains a serious problem in my home State of Kentucky where more than 80 Kentuckians die each month as a result of this epidemic. In fact, the demand for opiates has led to a heroin epidemic in Northern Kentucky, and heroin overdoses caused 61 deaths in this part of the State in 2012. Approving drugs with abuse-deterrent features is one tool among many available to FDA to help prevent prescription drug abuse. While much attention has been given to abuse-deterrent formulations for extended-release, long-acting opioids, what steps has FDA taken to encourage the development of these formulations in immediate release opiates? Furthermore, what is the rationale behind FDA’s decision not to require a Risk Evaluation and Mitigation Strategy (REMS) for immediate release opioids?

*Answer.* The FDA looks forward to a future in which most or all opioid analgesic medications—not just extended-release/long-acting (ER/LA) opioids products—are available in formulations that are less susceptible to abuse than the formulations that are on the market today. While ER/LA opioid analgesics typically contain larger amounts of drug and therefore carry a higher risk for overdose and death, abuse of immediate-release (IR) products is also a significant concern.

FDA plans to finalize guidance on the evaluation and labeling of all abuse deterrent opioid formulations, both IR and ER/LA, in the near future. The guidance—based, in part, on comments received during a public meeting held to discuss the development, assessment, and regulation of such products—will suggest the types of studies that should be conducted to demonstrate that a given opioid formulation has abuse-deterrent properties. The guidance will also discuss the evaluation of those studies and the labeling that may be approved based on the results.

FDA’s focus on incentivizing development and use of all opioid drug products with abuse-deterrent features has significantly increased interest in producing these products. Some 30 investigational new drug applications (INDs) have been submitted by manufacturers seeking to conduct clinical trials on potentially abuse-deterrent products. FDA is working with drug makers to advance the science of abuse deterrence and navigate the regulatory path to market as quickly as possible. Companies are exploring promising alternatives to currently marketed abuse-deterrent formulations in an innovative array of scientific techniques and approaches.

Additionally, abuse-deterrent opioid products, both IR and ER, may be eligible for one or more of FDA’s expedited review and approval programs, including fast track designation and priority review timelines, if they meet applicable criteria.

ER/LA opioid analgesics typically contain higher doses of opioids than IR opioids or opioid/non-opioid combinations products because they are intended to release the drug over a longer period of time. As a result, ER/LA opioid analgesics may be more desirable to individuals who misuse or abuse opioids—and pose a greater risk of fa-

tality in the event of an overdose. These concerns informed the FDA's decision to require the ER/LA Opioid Analgesics REMS.

FDA has received a citizen petition asking the agency to require IR opioids to include labeling changes that parallel those required of ER/LA opioid analgesics. The agency is in the process of reviewing and responding to that petition. If the agency determines that a REMS is necessary to ensure that the benefits of IR opioid analgesics outweigh the risks, we will take appropriate action.

*Question.* In a statement you released last year, strengthening surveillance efforts at FDA to actively monitor the prescription drug abuse epidemic and emerging trends was identified as a priority action item for the agency. It is my understanding that FDA has various surveillance methods either in place or in the pilot phase to monitor post-marketing safety issues. Will you please explain all of the post-marketing surveillance efforts underway at FDA related to prescription drug abuse, including if and how the Sentinel program will be used to support surveillance efforts related to prescription drug abuse trends? What other agencies is FDA coordinating with on surveillance efforts, and how is that coordination being implemented?

*Answer.* FDA actively monitors adverse event and medication error reports submitted by pharmaceutical manufacturers and the general public (e.g., doctors, nurses, patients, and family members of patients) through the FDA Adverse Event Reporting System (FAERS). FAERS, a key component of postmarketing surveillance, helps to identify new drug safety issues that were not observed during the clinical trials that served as the basis for drug approval. FDA safety evaluators regularly screen FAERS reports.

To supplement surveillance efforts, FDA has required new postmarketing studies for all ER/LA opioids. These studies will help to better assess the risks of misuse, abuse, addiction, overdose and death associated with long-term use of ER/LA opioids.

The Sentinel Program is a vital tool in FDA's surveillance efforts. Sentinel utilizes administrative healthcare claims data from healthcare providers and facilities and may at some point help us to understand issues brought to medical attention by patients prescribed opioids, once the claims for events such as overdoses are appropriately validated. As part of the required safety studies, FDA is requiring manufacturers to validate administrative claims that may be indicative of opioid overdoses. We are hopeful that this effort will yield reliable algorithms that can be used more broadly in administrative claims data, like Sentinel, to study these types of outcomes of prescription opioid abuse.

The agency is also collaborating in several efforts to collect more robust and comprehensive data on opioid abuse, including ER/LA opioid abuse. FDA is working with the National Center for Health Statistics at the Centers for Disease Control and Prevention (CDC) to obtain detailed national data on emergency department visits relating to drug abuse from hospitals participating in the new National Hospital Care Survey. FDA is also working with the National Electronic Injury Surveillance System—Cooperative Adverse Drug Event Surveillance Project (NEISS-CADES) to expand the data collection and abstraction process to include abuse-related clinical encounters. In addition, the agency is leading an ongoing collaborative project with CDC to identify and quantify deaths related to specific drugs, including those due to overdoses caused by prescription opioid products. Finally, FDA is exploring ways to use data from State-based Prescription Drug Monitoring Programs to better understand prescribing and dispensing behaviors of controlled substances that play a role in the evaluation of prescription drug abuse.

FDA is committed to making a difference in this epidemic. We continue to actively partner with others to implement the Administration's National Drug Control Strategy and Prescription Drug Abuse Prevention Plan—and reduce prescription drug misuse, abuse and addiction. FDA is also continuing its close participation in surveillance efforts through the Prescription Drug Abuse Subcommittee of the HHS Behavioral Health Coordinating Council.

*Question.* As you know, FDA approval of innovator drugs that lack abuse-deterrent features is a major concern in my home State of Kentucky. Why has FDA refrained from granting an abuse-deterrent label to products that meet the requirements of abuse-deterrence under any one of tiers 1, 2 and 3 of the FDA Draft Guidance for Industry on Abuse-Deterrent Opioids? How does FDA recognize and communicate, or plan to recognize and communicate, that although a product may not have the ability to meet the requirements outlined under all the tiers listed in the FDA Draft Guidance for Industry on Abuse-Deterrent Opioids, it may still offer technology that makes the product more difficult to abuse than others?

*Answer.* FDA has approved four ER/LA opioid analgesics with labeling describing the product's abuse-deterrent properties consistent with the draft guidance. They include: OxyContin; Targiniq ER; Embeda ER; and Hysingla ER.

We have rejected abuse-deterrent claims for products when the data were insufficient to support such claims. FDA will approve labeling describing a product's abuse-deterrent properties when the data show that a product's abuse-deterrent properties can be expected to result, or actually have resulted, in a meaningful reduction in that product's abuse.

We are still in the early stages of abuse-deterrent product development—the market has a small number of products using abuse-deterrent technologies, and the agency is assessing each opioid drug product's safety and efficacy on a case-by-case basis. FDA expects these technologies to improve and expects products containing them (both innovator and generic) to become more widely used. FDA looks forward to a time, hopefully not so far in the future, when the majority of opioids are in effective, abuse-deterrent forms; forms that substantially reduce abuse, including by oral, intranasal, and intravenous routes.

FDA hopes that the final guidance, to be released soon, will clarify abuse-deterrent labeling claims. Abuse-deterrent labeling will be approved for products. All abuse-deterrent labeled products can be expected to result, or will have actually resulted, in a meaningful reduction in that product's abuse.

*Question.* The incidence of newborns suffering withdrawal has tripled throughout the country since 2000. To put this in perspective, in 2009, approximately one infant was born each hour showing signs of drug withdrawal. In Kentucky, this condition increased more than 2,400 percent from 2000 to 2012. Babies suffering from drug dependence are more likely than other newborns to have complications such as low birth weight and respiratory complications, placing additional hurdles in place to becoming healthy and adding costs to the healthcare system. What activities is FDA involved in to address the rising number of babies being born dependent on opioids?

*Answer.* The agency is also alarmed by the dramatic increase in the number of babies born with Neonatal Opioid Withdrawal Syndrome (NOWS) and recently augmented the labeling warnings about this risk for ER/LA opioid analgesics. Product labeling is FDA's primary tool to inform prescribers about approved uses of medications and to assist them in making the best decisions for their patients.

For women with chronic pain, there are no analgesics that come without some risk to a developing fetus. Nonsteroidal anti-inflammatory drugs (NSAIDs) cannot be used during the third trimester. Other non-opioid medications used for the treatment of pain also have risks.

Given the risks associated with alternative products, opioid analgesics may be an appropriate treatment option during pregnancy. We are committed to providing the necessary information to prescribers and patients so that they may make informed decisions regarding appropriate use of these drugs during pregnancy.

As noted above, FDA is also continuing its close participation in surveillance efforts through the Prescription Drug Abuse Subcommittee of the HHS Behavioral Health Coordinating Council.

*Question.* Incidence of skin cancer continues to rise in the United States. One American dies every hour from melanoma, the deadliest form of skin cancer. We know that sun exposure is a high risk factor for melanoma and we know that using sunscreen effectively can reduce that risk. Yet, Americans still do not have access to sunscreen ingredients that have been on the market all over the world. To encourage the FDA to review the backlog of sunscreen applications that had been pending for more than a decade, Congress passed and I supported the Sunscreen Innovation Act, which was signed into law by President Obama last November. What steps are being taken by FDA to see that sunscreen ingredients that have been on the market and used safely all over the world are accessible to Americans?

*Answer.* It is very important that consumers have access to safe and effective preventive skin care drug products. FDA is actively working to assure that sunscreens containing the ingredients being evaluated under the Sunscreen Innovation Act (SIA) provide such protection.

As required by the SIA, FDA has completed several important steps in the review process for sunscreen active ingredient applications marketed for a material time and extent in other countries and determined eligible for review prior to enactment of the SIA. We have reviewed all eight pending sunscreen active ingredient applications, evaluated submitted data, and identified the missing information we need to determine that sunscreens containing each ingredient would be generally recognized as safe and effective. We have issued proposed orders outlining additional data needed in order to make a determination that each ingredient meets this standard.

As outlined in the SIA, the data requested must be gathered and submitted to the FDA for evaluation before the agency can proceed to a Final Sunscreen Order.

We look forward to receiving and reviewing the data. The agency is committed to doing its best to continue to meet future deadlines under the SIA—and to provide American consumers with additional options for safe and effective sunscreen ingredients.

Heightened concerns about the risk of skin cancer and premature aging have fundamentally altered consumers' use of sunscreen products over the past few decades. Americans once applied the products in modest amounts while at the beach or exercising during peak hours of summer sun exposure. In contrast today, Americans—young and old, fair-skinned and not—now routinely spread on sunscreens all year round.

A significant increase in the amount and frequency of sunscreen exposure combined with advances in scientific understanding that some sunscreen ingredients may be absorbed into the bloodstream have raised safety concerns.

The SIA does not relax FDA's scientific standards for evaluating safety and effectiveness or the requirement that the agency have adequate data on which to base a generally recognized as safe and effective (GRAS/E) determination. FDA has proposed data requirements, unanimously supported by an Advisory Committee panel of independent scientific experts, to meet this standard. We look forward to receiving and reviewing industry data—and helping American consumers make informed decisions about these products.

---

#### QUESTIONS SUBMITTED BY SENATOR STEVE DAINES

*Question.* Earlier this month, FDA took the significant step of approving the first biosimilar drug. It is disappointing, however, that important guidance is still not forthcoming from the agency on issues such as naming, interchangeability, and others. In fact, in the almost exactly 5 years since enactment of the biosimilars law, no final guidance on any biosimilars topic has come from FDA.

What is the anticipated timeline for these important guidance documents, which are essential to encouraging and assisting companies to develop biosimilars that will benefit patients?

*Answer.* While the agency cannot provide a specific timeline for the release of any guidance, FDA continues to clarify our approach to implementation of the BPCI Act and provide guidance and information to assist biological product developers—sponsors/companies—with bringing biosimilar and interchangeable products to market.

FDA has recently issued three final guidances:

- Scientific Considerations in Demonstrating Biosimilarity to a Reference Product
- Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product
- Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009

FDA has published the following draft guidances since 2012:

- Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product
- Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act
- Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants
- Biosimilars: Additional Questions and Answers Regarding Implementation of the BPCI Act of 2009

The agency is continuing to review the comments received as we move forward in finalizing these draft guidances. In addition, FDA expects to issue draft guidance in 2015 on the following topics identified in CDER's Guidance Agenda:

- Considerations in Demonstrating Interchangeability to a Reference Product
- Statistical Approaches to Evaluation of Analytical Similarity Data to Support a Demonstration of Biosimilarity
- Labeling for Biosimilar Biological Products
- Nonproprietary Naming for Biological Products

*Question.* Within 30 days, please provide the subcommittee with a list of biosimilars guidance documents you expect to publish this calendar year. With respect to any draft biosimilars guidance, please indicate when you expect to make that guidance final.

*Answer.* Please see the previous response.

## QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY

## STATE INSPECTION STANDARDS FOR FSMA

*Question.* The budget includes \$32 million to train approximately 1,000 State food safety inspectors, and to help the States implement real-time information sharing capacity with FDA. That comes out to training about 20 inspectors in each State, which isn't that many.

What oversight will FDA provide to make certain that State inspections are up to FDA standards, and how will they monitor the States?

*Answer.* For State inspections performed under FDA food inspection contracts, FDA will evaluate the contracted State agencies' overall performance throughout the contract period. Inspectional performance evaluation will include review of inspection reports, audit assessments and joint Federal/State inspections. State inspections will be collaboratively scheduled by the FDA district offices and each contracted State agency. In addition, there are 40 State-manufactured food regulatory programs enrolled in the Manufactured Food Regulatory Program Standards (MFRPS), which represents 89 percent of contracted inspections, which are used by the States as a guide for consistent, continuous improvement for State food manufacturing programs. MFRPS standards promote development of a high-quality State-manufactured food regulatory program and include a process for continuous improvement. The MFRPS are updated, when applicable, to facilitate compliance with new legislation, regulations, guidance, inspection programs, and agency rules as they are developed.

Finally, FDA recognizes the need to establish training programs for Federal and State inspectors who will conduct inspections on behalf of FDA for the new FSMA regulations. The expected outcome of the evaluation is to ensure competency in the performance and quality of inspections regardless of the regulatory entity that performs such inspections.

## IMPORTED FOOD INSPECTION

*Question.* GAO recently published a report regarding FDA's foreign offices and made a couple of significant findings. The first was that FDA is not conducting nearly the number of foreign inspections as FSMA mandated. They conducted approximately 1,300 inspections in 2012, and plan to conduct only 1,200 in fiscal year 2015. FSMA mandated 600 inspections in 2011, with a doubling of the previous years' inspection level for the following 5 years. The second finding was that 44 percent of foreign office positions were vacant as of October 2014.

I understand that the FDA has indicated that they don't intend to fulfill the FSMA mandate, and don't necessarily believe that would be useful.

However, how is FDA determining what the appropriate level of physical foreign inspections should be?

*Answer.* Under the FDA Food Safety Modernization Act (FSMA), FDA is directed to inspect at least 600 foreign food facilities in 2011 and, for each of the next 5 years, to inspect twice the number of facilities inspected during the previous year. FSMA provides FDA a multi-faceted toolkit to better ensure the safety of imported food. This toolkit includes increased foreign inspections, as foreign inspections provide direct accountability for inspected firms, incentives for all foreign firms exporting to the United States to comply with U.S. requirements, and critical intelligence for FDA concerning foreign food safety practices. The toolkit also includes sharpening private sector accountability for import safety, leveraging private sector resources, and taking advantage of any resources and services the foreign governments can provide to elevate assurances that food imported into the United States meets FSMA's prevention-oriented standards and requirements.

Foreign inspections are an important part of the new import safety system mandated by FSMA, but they cannot alone ensure comparable safety of imported and domestic food. FDA has been clear in its Report to Congress under section 110(a)(1) of FSMA that the agency does not anticipate going significantly beyond 1,200 foreign food facility inspections per year in the foreseeable future until after other parts of the new import safety system have been implemented. FDA's position is based on the enormity of the additional funding that would be needed to meet FSMA's foreign inspection goals, coupled with FDA's view that additional resources would be more effectively spent first on implementing tools in the FSMA import safety toolkit that leverage both FDA and private sector resources to ensure the safety of foods exported to the United States by foreign firms.

FDA is committed to allocating its resources using a risk-based inspection model for the selection of firms and the number of firms per country. This risk-informed approach is based on the strategic allocation of programmatic resources by inte-

grating in a systematic manner the relevant quantitative, qualitative, and deterministic public health safety factors to obtain a decision to select firms and countries. This approach better protects the safety of the U.S. food supply and gives the agency flexibility to adjust FDA resources effectively and efficiently as emerging issues arise.

FDA Centers and Offices work collaboratively on an inspection work plan each year. For example, the FDA India Office works with ORA and CFSAN to develop a work plan for food facilities inspections in India. The FDA India Office provides information to FDA headquarters regarding high-risk facilities and high volume facilities that have not been inspected. The FDA India Office requests other food facilities inspections based on local intelligence, e.g. complaints, informants, local news, and other sources. In March 2015, FDA signed a memorandum of understanding with the Indian competent authority that has oversight of some food exports. The FDA India Office hopes to be able to leverage information from this authority to further target high-risk food facilities that export to the United States.

Another example is from the FDA China Office. The FDA China Office develops a list of recommended firms for inspection to share with ORA and the Centers. Similar to the FDA India Office, the FDA China Office uses local intelligence to help select which firms should be included on the list in addition to those higher risk food facilities that have not had a previous inspection and are known to be active suppliers to the United States.

FDA also is working diligently to fill vacancies within our foreign offices. In fact, since the time of the GAO report, FDA has already reduced the vacancy rate from 44 percent to 40 percent.

*Question.* Since you aren't planning to fulfill the FSMA mandate, what is your plan?

*Answer.* As discussed, FSMA provides FDA a multi-faceted toolkit to better ensure the safety of imported food. For example, the foreign supplier verification programs mandated by FSMA will be the foundation of a new system under which importers will take greater responsibility for ensuring that foreign manufacturers produce food in compliance with U.S. safety requirements. Another import-related program, the Voluntary Qualified Importer Program (VQIP), will make it easier for participants in the program to import items into the United States, based on demonstrated high-performance in food safety, and enable FDA to better focus its resources on potentially higher risk imports. FSMA also directs FDA to establish an accredited third-party audit program, under which third-party auditors can assure importers and FDA that foreign producers are using effective preventive controls. Final rules requiring foreign supplier verification programs and establishing the accredited third-party audit program are scheduled to publish this year.

The agency is expanding its collaborations with foreign governments so that FDA can rely as appropriate on foreign government food safety programs and gain knowledge about the safety of foreign exports. This allows FDA to focus its own resources more efficiently.

FDA's current focus with respect to foreign facility inspections is targeting them to achieve the greatest public health benefit. FDA's selection of foreign food facilities for inspection is based on an overall, cross-cutting risk profile. The primary factors contributing to a facility's risk profile include: (1) the food safety risk associated with the commodity (the type of food), (2) the manufacturing process, and (3) the compliance history of the facility, such as refusal rates for products that were denied entry into the United States. In addition, section 201 of FSMA requires FDA to identify high-risk facilities and allocate resources to inspect facilities according to the known safety risks of the facilities, and includes several factors to consider when making that assessment.

FDA is committed to reconfiguring import screening and field exam activities to complement oversight of FSMA's foreign supplier verification requirement and ensure that FDA is making strategic, risk-based use of its import oversight resources. This initiative is documented in FDA's Operational Strategy for the Implementation of FSMA (<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm>). FDA is also committed to building data integration and analysis systems to strengthen risk-based targeting of resources. As FDA moves forward with implementing the new FSMA toolkit for imports, FDA intends to monitor, analyze, and reconsider a host of factors, including the number of foreign inspections we conduct and how we target establishments. FDA will adjust its plan as necessary, and as funding permits, to further our public health mission. All of these activities will contribute to FDA's ability to ensure comparable safety of imported and domestic food and also rely on FDA receiving sufficient resources.

*Question.* How has a vacancy rate that high affected the ability of the foreign offices to do their jobs, and how are you addressing this issue?

*Answer.* As noted in the GAO report, FDA has undertaken efforts to improve staffing in its foreign posts but has experienced some challenges. For example, following expanded funding under the China Safety Initiative, FDA's China Office has been working extensively and over an extended period of time with Chinese counterparts to obtain visas for an increased number of FDA staff to be based in China. In a positive development, the FDA signed two Implementing Arrangements (IAs) with its Chinese counterparts in November and December 2014. The documents, signed with China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and China's Food and Drug Administration (CFDA), frame the work of regulatory personnel posted in each country, outline the expectations of FDA and AQSIQ regarding inspections of food facilities, and detail the expectations of FDA and CFDA regarding inspections of drug facilities.

As of May 2015, there are now 11 FDA FTEs in the FDA's Beijing, China Office. This includes an additional seven staff who have recently been issued visas and deployed to the China Office. We have one foods investigator who is preparing to deploy, but has not yet applied for her visa. We currently also have two drug investigators on short-term detail. The FDA China Office is actively recruiting staff to reduce the current vacancies and is working closely with FDA's Office of Human Resources (OHR). FDA continues to augment the staff in China with temporary duty details and foreign cadre inspections to complete its inspectional work plans in China.

The FDA India Office also has faced recruitment challenges but is working to hire additional staff. At present, the FDA India Office has five positions filled, including two food investigators. The FDA India Office has set an inspection target for in-country investigators to ensure inspection performance expectations are met. For fiscal year 2014, FDA India Office food inspections met work plan goals. Fiscal year 2015 inspectional targets are currently on track to meet expectations. FDA will conduct inspections with temporary duty details and foreign cadre inspectors until full staffing is achieved.

More generally, to address some of the recruitment challenges for a foreign assignment, FDA's Office of International Programs has:

- Developed continuous vacancy announcements for multiple geographic sites to maximize the pool of applicants.
- Developed an SOP for foreign post renewals and extensions to remove obstacles to retaining staff.
- Created interview panels that include relevant Center involvement to promote the selection of subject matter experts knowledgeable about Centers' programs.
- Strengthened the OIP deployment process(es).
- Created temporary details.
- Made more strategic utilization of locally employed staff (LES) in foreign posts.
- Leveraged other U.S. Government agencies field deployment processes/programs.

Despite some challenges to recruit highly qualified investigators to our foreign offices, OIP has been successful in strengthening inspection capabilities in FDA's offices overseas. In the past year alone, FDA's foreign offices have increased the total number of inspections and expanded the countries in which foreign inspections are being conducted by in-country investigators and investigators on 60–120 day detail assignments to foreign offices.

#### FDA OFFICE OF REGULATORY AFFAIRS (FIELD STAFF) REORGANIZATION

*Question.* You started an initiative last year to reorganize your field staff in order to make them more specialized. The goal appears to be to have inspectors who are very focused on one type of inspection—drug facility inspections, for example, instead of having inspectors who have to play many different roles. With the increasing complexity of drug and food manufacturing, as well as FSMA implementation, this seems like a good idea.

Will this reorganization require additional funding and training? If so, how much?

*Answer.* FDA is working to realign inspection and compliance staff and managers by program (e.g. food, pharmaceutical, etc.). Training is a critical component of enhancing specialization of FDA's inspectorate and ensuring the staff has the expertise and tools needed to keep pace with changing and advancing technology in the industries FDA regulates.

As part of FDA's program alignment efforts, ORA is working with FDA Centers to evaluate current training programs, develop new and novel approaches for training staff, and work toward more collaborative training leveraging both Center and Field experts. FDA will train our staff, State partners, and educate industry on new regulations resulting from FSMA, FDASIA, and other recently enacted laws. At this

time, however, it is unclear whether or not the agency will require any additional resources or training related to the realignment effort.

*Question.* Do you anticipate hiring additional staff as part of this effort?

*Answer.* It is too early to precisely predict the Office of Regulatory Affairs' (ORA's) future staff requirements, transitioning from a geographically based management model to a program-based management model, where investigations, compliance, and operational managers are aligned by program. ORA is comparing its current staffing level with the staffing needs for each program area. This information, along with data from each program's inventory, will be used to determine the gaps in staffing by program area. Once this gap analysis is complete, ORA will begin aligning staff to the new program management model and employ specific hiring requirements by program.

*Question.* How will you make sure the inspection staff is properly allocated across the country?

*Answer.* As FDA works to align inspection and compliance staff and managers, FDA is evaluating the current inventory of regulated firms across the country and across the globe. In the past decade, FDA has seen unparalleled growth of imported products which necessitates FDA to allocate staff across the United States based on domestic industry and at ports of entry and in foreign countries to ensure protection of the American public. FDA will align current staff not only by program but also by operational needs ensuring staff will be best positioned to inspect, examine, and collect samples of both domestic and imported products. In addition, FDA will target any inspectional hiring in those specialties and locations where there is a need.

#### ELECTRONIC DRUG INSERTS

*Question.* FDA recently published a rule requiring electronic-based labeling for healthcare providers, but there have been many concerns raised about them. The ag report last year actually included language directing FDA not to publish a rule that would require electronic labeling in lieu of paper inserts. Concerns raised include cybersecurity issues, a lack of access to the Internet in parts of rural America, and the loss of Internet access everywhere during a time of disaster. I understand that this rule only applies to healthcare providers and not packages provided directly to patients, but I believe these concerns are still valid.

Why did FDA move forward on this rule, and will these issues be addressed in the final rule?

*Answer.* On December 18, 2014, FDA issued a proposed rule entitled "Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products." We believe that this proposed rule addresses the Committee's concerns about the use of electronic labeling, while at the same time ensuring that the most up-to-date prescribing information is available for use by healthcare providers.

If finalized as proposed, this rule would generally require that prescribing information intended for healthcare professionals be distributed electronically, but also provide for continued access to prescribing information in paper format in a number of circumstances. For example, the proposed rule allows for drugs to be exempted from electronic-only distribution if electronic-only distribution could adversely affect the safety, effectiveness, purity, or potency of the drug; is not technologically feasible; or is otherwise inappropriate. Also, the proposed rule requires manufacturers to provide a toll-free telephone number that healthcare providers can call 24 hours a day, 7 days a week to request a paper copy of the label.

FDA would like to emphasize that this is a proposed rule, subject to notice-and-comment procedures. We granted a request to extend the comment period for 60 days, until May 18, 2015. FDA will consider all comments submitted in response to the proposal as we work to finalize the rule. We fully expect that the concerns you have raised will be addressed through that process.

#### FOOD SAFETY CENTERS OF EXCELLENCE

*Question.* As you know, CFSAN has for a number of years supported several Food Safety Centers of Excellence that help to support the food safety research needs of the FDA through basic research and various other tasks. The Committee has long been supportive of the work of these Centers.

Can you please provide some background on Food Safety Center of Excellence funding for fiscal year 2015 and fiscal year 2016, and whether or not there will be an increase in basic research support levels in fiscal year 2016?

*Answer.* The FDA Food Safety Centers of Excellence (COEs) support critical collaboration between FDA and academic institutions to advance regulatory science through innovative research, education, and scientific exchanges.

In fiscal year 2014 CFSAN awarded \$11.025 million in funding to the COEs. While FDA intends to maintain strong support for these Centers, final decisions on precise funding amounts for fiscal years 2015 and 2016 are still pending.

---

QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

FDA OVERSIGHT OF ANTIBIOTIC USE AND RESISTANCE

*Question.* Commissioner Hamburg, I am pleased to know that your agency expects drug companies to fully participate in the agency's policy for withdrawing growth-promoting uses of medically important antibiotics in food animals. To what extent does the agency expect this policy to reduce antibiotic use in agriculture? Does the agency have specific performance goals for this policy?

*Answer.* FDA is confident that the changes outlined in Guidance for Industry (GFI) #213 will be fully implemented by the December 2016 target date. These measures will significantly change how these drugs have been used for decades. Production uses of medically important antimicrobials will be eliminated as will over-the-counter access to the remaining therapeutic uses of these products in the feed or water of food-producing animals. In addition to tracking completion of these changes, FDA is enhancing data sources in a number of ways to help monitor the effects of GFI #213 over time. For example, FDA intends to publish a proposed regulation that would enhance the quality and utility of antimicrobial drug sales and distribution data it receives on antimicrobial drugs intended for use in food-producing animals by requiring reporting of such data by animal species. FDA is also working with State partners to perform whole genome sequencing on samples collected under the National Antimicrobial Resistance Monitoring System (NARMS), which will provide unprecedented data on the traits of resistant strains of foodborne bacteria from animals and animal-derived foods. Further, FDA is working with the Centers for Disease Control and Prevention (CDC) and the United States Department of Agriculture (USDA) to develop a plan for collecting additional data on antibiotic use and resistance to help provide a comprehensive, objective, and balanced summary assessment of antibiotic drug use and resistance in animal agriculture. FDA is continuing to work with USDA and CDC in developing this plan and expects to hold a public meeting in the summer of 2015 to obtain input from the public.

*Question.* Commissioner Hamburg, I am concerned that some antibiotics approved for disease prevention or control do not have an explicitly defined duration or use or may be approved for use at a sub-therapeutic dose. What steps is the agency going to take to ensure these antibiotics are not used inappropriately in agriculture?

*Answer.* As FDA moves forward with implementing the changes outlined in Guidance for Industry (GFI) #213, FDA is also focusing on the remaining therapeutic uses of those products and evaluating whether additional improvements can be made to better align those uses with current antibiotic stewardship principles. For example, concerns have been raised about the use of medically important antibiotics for prevention purposes. FDA considers uses that are associated with the treatment, control, and prevention of specific diseases to be therapeutic uses that are important for assuring the health of food-producing animals, but would not consider the administration of a drug to apparently healthy animals in the absence of any information that such animals were at risk of a specific disease to be judicious. In addition, when such uses of medically important antibiotics are deemed necessary, it is important that the duration of administration be appropriately limited. Therefore, as part of FDA's overall effort to ensure the judicious use of medically important antibiotics, FDA is currently developing a process and timeframe for evaluating and addressing that issue.

*Question.* Commissioner Hamburg, I strongly support your agency's move to bring antibiotics under veterinary oversight. In your policy on judicious antibiotic use, you establish guidelines for veterinarians to consider when directing that an antibiotic be used for disease prevention, such as using antibiotics only for animals at risk of developing an infection and when no other reasonable alternatives exist. What steps is the agency going to take to ensure these guidelines are followed?

*Answer.* In highlighting the importance of veterinary oversight of medically important antibiotics, FDA noted in Guidance for Industry (GFI) #213 that veterinarians in the course of their professional practice take into consideration a number of relevant factors for determining the risk of a specific bacterial disease and for determining whether the use of medically important antimicrobials for prevention purposes is appropriate in a particular situation. These factors include whether: (1) there is evidence of effectiveness; (2) such a preventive use is consistent with accepted veterinary practice; (3) the use is linked to a specific etiologic agent; (4) the use

is appropriately targeted to animals at risk of developing a specific disease; and (5) no reasonable alternatives for intervention exist.

A critical step that is being taken through implementation of GFI #213 is to change the over-the-counter (OTC) status of these products so that licensed veterinarians have an oversight responsibility and are in a position to ensure that factors such as those described above are taken into consideration. Once the feed use products are changed from OTC to Veterinary Feed Directive (VFD) status, veterinary authorization of these products must be done in compliance with the procedures described in the VFD regulation. In conjunction with implementing the updated VFD regulation, FDA intends to enhance its inspectional activities to ensure compliance with the VFD requirements. FDA is also directing resources towards education and training on the VFD process and on judicious use. FDA is also engaging veterinary and producer organizations in this issue, as they play a key role in veterinarians' practical application of judicious use principles at the farm level. FDA is very encouraged by the strong commitments organizations like the American Veterinary Medical Association have made to this effort.

*Question.* Commissioner Hamburg, Congress provided an additional \$3 million for the National Antimicrobial Resistance Monitoring System (NARMS) in fiscal year 2015, and this increased funding level was requested in the fiscal year 2016 budget. Can you describe how your agency will use these increased funds to make critical improvements to NARMS, and how these improvements will allow it to collect statistically valid data on antibiotic resistance trends in foodborne pathogens and to identify more outbreaks involving antibiotic-resistant pathogens?

*Answer.* FDA is using the extra funds to collect additional retail meat samples for the analysis of antimicrobial resistance and to implement advanced technologies in molecular characterization to improve microbial analysis.

Prior to its receipt of the additional monies, NARMS was only able to sample approximately 6500 retail meats, resulting in the recovery of 300–500 *Salmonella* isolates. This did not provide enough data for statistically valid analysis of antimicrobial resistance trends for most products. With the additional monies NARMS is working to increase the number of samples tested by the current participating laboratories and expand testing to include additional geographic areas not currently under surveillance. With these changes FDA will be able to collect enough *Salmonella* isolates to improve the statistical confidence around NARMS resistance trends, thereby making NARMS data more useful for regulatory decisionmaking. This enhancement also meets Sub-Objective 2.4.1 of the White House's National Action Plan for Combating Antibiotic Resistant Bacteria, "Enhance surveillance of antibiotic resistance in animal and zoonotic pathogens and commensal organisms by strengthening NARMS and leveraging other field- and laboratory-based surveillance systems."

The advent of whole genome sequencing (WGS) is poised to vastly improve the microbiology and epidemiology of infectious diseases. At relatively low costs, comprehensive genetic information can be gleaned in a short time. With the enhanced funding, NARMS has been able to continue efforts to implement WGS, as well as the information technology and bioinformatics infrastructure needed to sustain it, through the purchase of additional equipment, software, and reagents. Furthermore, NARMS now has the capacity to sequence all *Salmonella* isolates collected from retail meats from 2002 (the inception of the retail meat program) to present. By expanding the whole genome sequence database with retail meat isolates collected through NARMS, FDA will greatly improve the detection of foodborne outbreaks, the attribution of resistant infections, and research on the evolution and spread of resistant bacteria in the food supply, among other things. By the end of the year, NARMS will publish the sequence information and accompanying metadata for all retail *Salmonella* isolates tested through 2014.

---

#### QUESTIONS SUBMITTED BY SENATOR PATRICK J. LEAHY

##### FOOD SAFETY MODERNIZATION ACT

*Question.* The premium Vermont brand depends on adhering to the highest standards of quality and food safety. However, Vermont's diversified farms are very concerned that implementation of the Food Safety Modernization Act may crush them under a burden of fees, paper work, and poorly targeted and confusing rules. I appreciate that your food safety team, led by Mike Taylor, has visited Vermont several times and has listened many of my constituent's concerns, resulting in better rules, yet many questions still remain for our farmers and our State agencies.

The budget request includes an increase of \$109.5 million for a total of a total of \$1.3 billion in budget authority for FSMA implementation. By your own estimate this leaves a gap of \$166 million. I am worried that your budget falls short on the needs for your State partnerships, staff training, and education and technical assistance for producers and value added agriculture.

With this gap and your current funding request, please explain to me how you are going to educate before you regulate?

*Answer.* In addition to the increase of \$109.5 million in Budget Authority, FDA has also proposed an additional \$191.8 million in User Fees. Taken together, FDA believes this additional \$301.2 million will allow FDA to fully implement FSMA.

FDA intends to continue partnering with other Federal, State, and foreign government agencies and organizations; land grant universities and other academic institutions; produce farm and food industry associations; and food safety professional organizations during the implementation phase. We remain committed to increasing education and accessibility to technical assistance to foster and facilitate compliance. At our recent public meeting on the implementation strategy for the FSMA rules, we received additional input from the public on the best ways for us to help educate industry to assist in compliance and improve public health. However, FDA's ability to complete the activities described depends on receiving the proposed funding in the fiscal year 2016 President's budget. Without this funding, these activities would need to be scaled back.

#### DIETARY GUIDELINES

*Question.* The FDA's Dietary Guidelines Advisory Committee (DGAC) recommended on February 19, 2015, an update to the Dietary Guidelines and urged the FDA to re-consider its advice that pregnant women or those that may become pregnant eat no more than 6 ounces of albacore tuna per week, concluding that "for the majority of commercial wild and farmed species, neither the risks of mercury nor organic pollutants outweigh the health benefits of seafood consumption, such as decreased cardiovascular disease risk and improved infant neurodevelopment." A number of consumer and public health stakeholders have raised significant concerns with the reliability of the risk/benefit risk analysis on which the recommendation is based as compared to the volumes of peer reviewed literature on which the current tuna consumption advisory is based.

How will the FDA have reconcile the new risk benefit approach recommended by the Dietary Guidelines Advisory Committee with the established scientific literature to publish final guidelines that best promote public health?

*Answer.* In developing the draft updated fish consumption advice released in June 2014, FDA and EPA reviewed the totality of the scientific evidence, including the research that influenced the recommendation in the Dietary Guidelines for Americans 2010. That totality of science included evidence on the harmful effects of methylmercury and beneficial effects from eating fish. In addition, an FDA analysis of seafood consumption data from over 1,000 pregnant women in the United States found that 21 percent of them ate no fish in the previous month. Those who ate fish ate far less than the Dietary Guidelines for Americans recommends, with 50 percent eating fewer than 2 ounces a week.

Before issuing final advice, FDA and EPA committed to accepting and considering public comment as well as seeking the advice of the FDA's Risk Communication Advisory Committee (RCAC). RCAC held a public meeting on the draft updated advice on November 3–4, 2014, which provided a forum for open discussion of the issues. The public comment period closed on March 26, 2015.

The agencies are now considering the public comments and whether any modifications to the advice are needed. We expect this process to be completed in 2015. Please be assured that completing the updated advice remains a priority.

#### SUBCOMMITTEE RECESS

Senator MORAN. This subcommittee will meet again at 10 a.m. on Tuesday, March 17. Our witness will be the Secretary of Agriculture, Secretary Vilsack.

We thank you all for your presence. Wish you well, Commissioner, in your future endeavors.

Dr. HAMBURG. Thank you.

Senator MORAN. I thank everyone for their attendance. This meeting is adjourned.

[Whereupon, at 11:34 a.m., Thursday, March 12, the subcommittee was recessed, to reconvene at 10 a.m., Tuesday, March 17.]

**AGRICULTURE, RURAL DEVELOPMENT, FOOD  
AND DRUG ADMINISTRATION AND RELATED  
AGENCIES APPROPRIATIONS FOR FISCAL  
YEAR 2016**

---

**TUESDAY, MARCH 17, 2015**

U.S. SENATE,  
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,  
*Washington, DC.*

The subcommittee met at 10:02 a.m. in room SD-192, Dirksen Senate Office Building, Hon. Jerry Moran (chairman) presiding.

Present: Senators Moran, Blunt, Cochran, Collins, Hoeven, Daines, Merkley, Tester, and Udall.

**DEPARTMENT OF AGRICULTURE**

**STATEMENT OF HON. THOMAS J. VILSACK, SECRETARY**

**ACCOMPANIED BY:**

**DR. ROBERT JOHANSSON, ACTING CHIEF ECONOMIST**

**MR. MICHAEL L. YOUNG, BUDGET OFFICER**

**OPENING STATEMENT OF SENATOR JERRY MORAN**

Senator MORAN. The subcommittee will come to order. Senator Merkley, the ranking member, is en route. We have a time challenge today. Two votes are scheduled at 11:00. And so we're going to forego opening statements. Senator Merkley and I will make no comments more than what I'm making right now. And Secretary Vilsack, welcome.

What I think will happen at around 11 o'clock is that we will have a rotating chairman of this subcommittee, so that during the first vote, I will go vote and come back, and then as the second vote is called, my hope is that we have concluded our hearing. So we will try to keep this going, and mostly directed toward statements.

**PREPARED STATEMENT**

Let me thank you for your public service, your care for farmers and ranchers of our country. Thank you for this weekend being at the National Farmers Union annual meeting, this time in Wichita, Kansas. We are delighted to have you in our State.

[The statement follows:]

**PREPARED STATEMENT OF SENATOR JERRY MORAN**

This hearing will come to order. Good morning. The purpose of today's hearing is to discuss the Department of Agriculture's fiscal year 2016 budget request, and thank you to Secretary Vilsack, Dr. Johansson, and Mr. Young for being here today.

Secretary Vilsack, I enjoyed getting to visit with you the other day and look forward to having another discussion about the Department's budget and priorities for the year.

Agriculture remains one of the bright spots in our nation's economy, supporting more than 16 million jobs nationwide and forming the backbone of our rural communities. American farmers and ranchers are the best at what they do when given the opportunity to compete on an even playing field.

After a long, arduous process and a great deal of economic uncertainty, Congress enacted the Agricultural Act of 2014 one year ago. The Farm Bill authorized sweeping changes to commodity and crop insurance programs, consolidated and reinforced conservation efforts, and reauthorized vital research and rural development programs. Agriculture is Kansas's #1 industry—directly responsible for 37 percent of the state's economy. Enactment of a new Farm Bill was welcome news for producers, research institutions, and rural communities in my home state.

It is now the responsibility of this Committee to continue oversight of Farm Bill implementation and provide USDA the resources it needs to ensure its effectiveness. Producers are facing a series of important decisions for their operations in the coming weeks, and the Department's guidance will be vital in educating farmers to determine which program best suits their interests.

The challenges farmers and ranchers face are not limited to factors in their control. Unpredictable weather conditions and volatile foreign markets wreak significant impacts on a producer's bottom line. Many parts of the country are still suffering from persistent drought conditions, and this year's snowpack deficit appears to offer little relief to western states. Pests and diseases also pose significant threats to plants and animals—and their respective industries—as we are witnessing with citrus greening and avian influenza. Investments in agriculture research help mitigate these impacts, both environmentally and economically, and prepare producers for future adverse conditions.

This year's budget request for the Department of Agriculture proposes a \$900 million increase above the enacted levels in fiscal year 2015. I support many items in the request, but we must work to prioritize investments based in fiscal reality. As Chairman, I look forward to working with Senator Merkley and other members of the subcommittee to identify those priorities and make the most effective and efficient decisions on behalf of American taxpayers.

I look forward to discussing these issues and others with our witnesses today. I would now like to turn to our Ranking Member, Senator Merkley, for his opening statement.

Senator MORAN. And Senator Merkley, it is my understanding we have both agreed to no opening statements, although I may have just violated that. And I have called the meeting to order. I would defer to the Senator from Oregon.

Senator MERKLEY. Well, thank you very much. I'm delighted to be here, and I'm happy for us to expeditiously proceed.

Senator MORAN. Recognize the Secretary of Agriculture, Secretary Vilsack.

#### SUMMARY STATEMENT OF HON. THOMAS J. VILSACK

Secretary VILSACK. Mr. Chairman, thank you very much, and I certainly appreciate the opportunity to be here.

[The statement follows:]

#### PREPARED STATEMENT OF HON. THOMAS J. VILSACK

Mr. Chairman and distinguished members of this Subcommittee, I appreciate the opportunity to appear before you to discuss the Administration's priorities for the Department of Agriculture (USDA) and provide you an overview of the President's 2016 budget. Joining me today are Robert Johansson, USDA's Acting Chief Economist, and Michael Young, USDA's Budget Officer.

The President's budget strengthens the middle class and helps America's hard-working families get ahead in a time of relentless economic and technological change. Investments made by USDA work together to support the most productive agricultural sector in the world, attract and retain a talented labor force, improve connectivity and access to information in rural communities, move more American-grown products to market, and make rural communities places where businesses—

farm and non-farm alike—want to innovate, grow, and create more good paying jobs. These investments reward hard work, generate rising incomes, and allow everyone to share in the prosperity of a growing America.

In the past 6 years, USDA assisted more than 900,000 rural families to buy or refinance a home, helping 146,000 rural Americans become homeowners in fiscal year (FY) 2014 alone. Since 2009, we have invested a total of \$48.3 billion in new or improved infrastructure in rural areas, which helped 15.7 million rural residents get access to clean drinking water and better waste water disposal. Modernized electrical service was delivered to more than 5.5 million subscribers. More than 21,000 grants and loans helped approximately 89,000 rural small businesses grow, creating or saving an estimated 418,000 jobs between fiscal year's 2009 and 2014.

We have also continued our StrikeForce Initiative, which represents a broad commitment to increase investments in poverty-stricken rural communities through intensive outreach and stronger partnerships with community organizations. Since the inception of StrikeForce in 2010, USDA has partnered with almost 500 community and faith-based organizations, businesses, foundations, universities and other groups to support 109,000 projects with almost \$14 billion in investments in rural America. We are providing a pathway to success and expanding the middle class.

Critical to our efforts is the 2014 Farm Bill, which enhanced the array of authorities and resources to improve agricultural productivity, to strengthen the foundation for helping rural communities prosper, to enhance the resiliency of forests and private working lands, and to ensure access to a safe, diverse and nutritious food supply. Farmers, ranchers and those working in supporting industries maintain an agriculture sector that has seen strong growth over the past 6 years. Agriculture and agriculture-related industries account for about \$775.8 billion in economic activity, support one out of every 11 jobs in the economy, and help to maintain vibrant, thriving rural communities.

The Department has completed implementation of many new Farm Bill authorities. This includes major new safety net programs providing certainty to American agricultural producers going into the 2015 crop year. We have made available over \$5 billion in critical assistance to producers across the country since sign-up for the disaster programs began on April 15, 2014. Significant new crop insurance protections were also made available. America's new and beginning farmers and ranchers, veteran farmers and ranchers, and women and minority farmers and ranchers were given improved access to credit.

In fiscal year 2014, exports of U.S. food and agricultural products set a new record, reaching \$152.5 billion and supporting nearly one million jobs here at home. Agricultural exports have climbed more than 58 percent in value since 2009, totaling \$771.7 billion over the past 5 years. Agricultural exports have increased in volume, demonstrating an increasing global appetite for American-grown products. Between 2009 and 2014, more than 6,000 U.S. companies participating in USDA-endorsed trade shows reported total on-site sales of more than \$1.3 billion and more than \$7.2 billion in 12-month projected sales. Rural exports support farm income, which translates into more economic activity in rural areas. In 2012, each dollar of agricultural exports stimulated another \$1.27 in business activity. As requested by the President, we need trade promotion authority to protect our workers, protect our environment, and open new markets to products stamped "Made in the USA."

USDA is also helping producers tap into growing consumer demand for locally-grown and organic food. USDA data indicate that local food sales totaled at least \$6.1 billion in 2012. Demand for organic food products also continues to grow and this sector now accounts for \$35 billion in annual U.S. sales. In 2013, the National Organic Program helped an additional 763 producers become certified organic, an increase of 4.2 percent from the previous year.

USDA's investments support strong local and regional supply chains and the rural jobs that come with them. Since 2013, USDA has made over 500 investments in local food infrastructure and direct marketing opportunities to help connect farmers and consumers and create jobs all along the supply chain for local food. In addition, USDA has made expanding SNAP recipients' access to fresh fruits and vegetables through farmers markets a priority in recent years. In 2008, about 750 farmers markets and direct marketing farmers accepted SNAP. As of January 2015, over 5,300 participated in markets accepting SNAP.

USDA continues to work with land-grant universities to deliver science-based knowledge and practical information to farmers, ranchers and forest landowners to support decisionmaking, innovation and economic opportunity. USDA leverages its research by making data more widely available. In 2014, 60 new cooperative research and development agreements were executed, 119 patent applications were filed, 83 patents were received, and 412 income-bearing license agreements were in effect. As authorized by the Farm Bill, USDA created the \$200 million Foundation

for Food and Agriculture Research, which will advance the research mission of the Department and foster collaboration with public and private research efforts.

Advances in biotechnology require thorough review by USDA before being approved, a practice commonly call deregulation. USDA needs to complete its review in a timely manner to facilitate planning and adoption of new technologies. To address this need, in 2012, USDA streamlined and improved the process for making determinations on petitions involving biotechnology. Because of the enhancements, we reduced the length of the petition review by over 600 days for petitions that do not require an environmental impact statement (EIS). USDA estimates that the cumulative number of actions taken to deregulate biotechnology products based on a scientific determination that they do not pose a plant pest risk will increase from a cumulative total of 87 actions in 2011 to an estimated cumulative total of 119 actions in 2016.

USDA's conservation efforts have enrolled a record number of acres in programs that have saved millions of tons of soil, improved water quality, preserved habitat for wildlife and protected sensitive ecological areas. To accomplish these goals, USDA has expanded beyond its traditional conservation programs and partnered with a record number of farmers, ranchers and landowners on landscape-scale conservation projects since 2009. As an example, under the newly authorized Regional Conservation Partnership Program (RCPP), USDA funded 115 projects that will build on the results achieved by USDA's traditional programs. RCPP empowers communities to set priorities and lead the way on conservation efforts important for their region. Such partnerships also encourage private sector investment so we can make an impact that's well beyond what the Federal government could accomplish on its own.

USDA continues to lead the way for renewable energy by supporting the infrastructure needed to grow the new energy economy. In 2014, more than 500 new awards under the Rural Energy for America Program helped USDA to reach a milestone of adding more than 8,000 projects between 2009 and 2014. Currently, REAP funds a total of 10,800 projects around the country to help producers and rural businesses save energy and increase their profitability. To support farmers producing biomass for renewable energy, USDA offered insurance coverage for farmers growing biofuel crops like switchgrass and camelina, and we are helping identify American farmland most suitable for growing energy crops. Under expanded authority provided by the 2014 Farm Bill, we are working to expand the number of commercial biorefineries in operation that produce advanced biofuels from non-food sources through the Biorefinery Assistance Program. We also took new steps to support biobased product manufacturing that promises to create new jobs across rural America—including adding new categories of qualified biobased products for Federal procurement and establishing reporting by Federal contractors of biobased product purchases.

Combating foodborne illness is one of our top priorities. In 2013, the Food Safety and Inspection Service (FSIS) developed the Salmonella Action Plan that outlines the measures FSIS will employ to achieve lower contamination rates in agency regulated products. The Plan includes strategies, such as the newly developed performance standards for ground poultry and chicken parts that will reduce illnesses. In addition, the recently implemented poultry inspection system will prevent an additional 5,000 foodborne illnesses each year through the improved control of Salmonella and Campylobacter.

The Administration strongly supports the Supplemental Nutrition Assistance Program (SNAP) and other critical programs that reduce hunger and help families meet their nutritional needs. SNAP is the cornerstone of the Nation's nutrition assistance safety net, touching the lives of millions of low-income Americans, the majority of whom are children, the elderly, or people with disabilities. SNAP kept over 5 million people, including nearly 2.2 million children, out of poverty in 2013. Recent research has shown that SNAP not only helps families put food on the table, but it has a positive long-term impact on children's health and education outcomes. We also support the ongoing implementation of the Healthy, Hunger-Free Kids Act. Over 90 percent of schools report that they are successfully meeting the new nutrition standards, serving meals with more whole grains, fruits, vegetables, lean protein and low-fat dairy, and less sodium and fat.

We must continue our efforts to address the challenges that continue to confront rural America. The 2016 budget builds on our success and proposes a set of investments to spur innovation, create new markets and job opportunities, enhance climate resiliency, improve access to a safe, nutritious food supply, and modernize infrastructure.

USDA's total budget for 2016 we are proposing before this Subcommittee is \$144 billion, of which approximately \$124 billion is mandatory funding. The majority of

these funds support crop insurance, nutrition assistance programs, farm commodity and trade programs and a number of conservation programs. The budget includes mandatory funds to fully support estimated participation levels for the Supplemental Nutrition Assistance Program (SNAP) and Child Nutrition programs. For discretionary programs of interest to this Subcommittee, our budget proposes \$20 billion, approximately \$908.5 million above the 2015 enacted level. That level fully funds expected participation in the Special Supplemental Nutrition Program for Women, Infants, and Children. It includes the funding needed to meet our responsibility for providing inspection services to the Nation's meat and poultry establishments. The budget also includes over \$1 billion to renew approximately 255,000 expiring contracts for rental assistance and includes new authorities to ensure the long term sustainability of this program.

Agriculture is an engine of growth and prosperity, directly or indirectly supporting 16 million jobs. The 2016 budget provides a strong farm safety net and makes investments to meet challenges of a competitive global market, changing climate, and making agriculture a reality for new and beginning farmers. The budget proposes a loan level of about \$6.145 billion for direct and guaranteed farm ownership and operating loans, 85 percent of which will be made to beginning farmers and ranchers and socially disadvantaged producers. The budget also includes about \$4 million to help new and beginning farmers and ranchers overcome the barriers they face when entering agriculture. In addition to providing funding to establish a Military Veterans Agricultural Liaison as authorized by the 2014 Farm Bill, the budget also establishes a \$2.5 million program to help veterans develop farming and ranching skills needed to become producers.

The rural economy will be even stronger because of the investments in rural infrastructure made by USDA. We will make over \$1 billion in investments in rural businesses estimated to provide approximately 32,000 jobs in rural areas. Over \$2.2 billion targeted to community facilities will expand educational opportunities for students, facilitate delivery of affordable healthcare, and ensure the availability of reliable emergency services. Funding for broadband is more than doubled. Through a pilot called Rural Corps, USDA will work in partnership with local organizations to deploy highly trained staff and increase the likelihood that investments in infrastructure and economic development are strategic, creating jobs and long-term economic benefits. In 2016, USDA will provide over 170,000 rural residents the assistance needed to become homeowners by making available nearly \$25 billion in loans to increase housing opportunities in rural area. Approximately \$900 million in direct loans will ensure that the very-low and low-income borrowers with the ability to repay mortgage debt are provided with a vehicle to access mortgage financing for homes located in rural areas.

Despite these investments, 85 percent of America's persistent poverty counties are in rural areas and rural childhood poverty rates are at their highest point since 1986. To address this need, \$20 million is provided for a Rural Child Poverty initiative, which would support innovative strategies to combat rural child poverty through a demonstration program. Additionally, funding is more than doubled for the Community Facilities Grant Program, which enables USDA to support investments in high-need areas and also leverage partnerships aimed at reducing child poverty, such as co-locating healthcare, nutrition assistance, and job-training programs. In both cases, this funding will be used in rural areas experiencing severe economic distress, such as StrikeForce, Promise Zones, and Tribal areas.

Access to a plentiful supply of safe and nutritious food is essential to the well-being and productivity of all Americans. As many as 200,000 families with children could benefit each year, beginning in the summer of 2016, from the proposed expansion of summer EBT demonstration projects, including \$67 million to support the second year of the Summer Electronic Benefit Transfer (EBT) pilot to reduce food insecurity among urban and rural children during the summer months when school meals are not available. The budget also includes \$35 million in school equipment grants to aid schools in serving healthy meals and provides continued support for other school-based resources. The budget proposes an additional \$25 million to bolster SNAP Employment and Training programs, which will allow some of our nation's poorest individuals to work toward self-sufficiency and continue to receive critical food assistance while doing so. Nationwide, USDA estimates that 23.5 million people, including 6.5 million children, live in low-income areas without easy access to a supermarket. To expand access to nutritious foods, the budget invests \$13 million in a newly authorized Healthy Food Financing Initiative that will provide funding for developing and equipping grocery stores and other small businesses and retailers selling healthy food in communities that currently lack these options. Americans will be better protected from foodborne illness with nearly 23,000 fewer illnesses projected in 2016 from 2014 as a result of improved food inspection.

Food for Progress and the McGovern-Dole International Food for Education and Child Nutrition Program will continue to provide benefits to millions of people overseas. These programs have helped to engage recipient countries not only by delivering food assistance, but also by fostering stronger internal production capacity and infrastructure, generating employment, boosting revenue, and developing new markets and productive economic partnerships. The budget provides \$20 million to support the local and regional procurement of food aid commodities for distribution overseas to complement existing food aid programs and to fill in nutritional gaps for targeted populations or food availability gaps caused by unexpected emergencies. Also, the budget proposes the authority to use up to 25 percent of Title II resources for these types of flexible emergency interventions that have proven to be so critical to effective responses in complex and logistically difficult emergencies.

USDA research plays a key role in fostering innovation and advancing technologies that increase the efficiency, sustainability, and profitability of American agriculture. Economic analysis finds strong and consistent evidence that investment in agricultural research has yielded high returns per dollar spent. The budget includes an increase of \$125 million for the Agriculture and Food Research Initiative. Funding for USDA's role in Federal efforts combatting anti-microbial resistant bacteria and improving pollinator health totals \$77 million and \$79 million, respectively. As part of the Administration's multi-agency initiative to support continued investment and innovation in the manufacturing sector, the budget also includes \$80 million to support two new Federal-private manufacturing institutes, with one dedicated to advanced biomanufacturing, while the other will focus on development of nanocellulosics. Investments to upgrade the Department's aging laboratory infrastructure include \$206 million to fully fund five priority construction and renovation needs, as identified in the Congressionally-mandated report issued by the Department in 2012.

To enhance resilience to climatic events, the budget provides \$200 million for the Watershed and Flood Prevention Operations (WFPO) to help communities adapt to changing natural resource conditions and climate change, and to minimize the impacts of natural disasters, including coastal flooding. USDA will utilize the broad authorities of WFPO to help communities create more resilient infrastructure and natural systems.

To protect the integrity of the programs we administer, we continue to work aggressively to identify and eliminate waste, fraud, and abuse. Program integrity is critical to the overall success of the programs we administer and funds must be used properly to earn America's trust that these programs deliver results while protecting taxpayer dollars. The budget builds on existing efforts and provides strategic increases, including an increase of \$14.5 million to automate and streamline reporting, increase operational efficiency, reduce improper payments, and otherwise enhance program integrity for Child Nutrition Programs. The budget requests an additional \$4 million to ensure that States are meeting the highest standards of program integrity in administering SNAP. The budget also includes \$2.1 million for the Risk Management Agency to enhance regulatory compliance, with a focus on improving error rate sampling for improper payments.

While providing record levels of service to rural America, USDA has improved management operations. Through the Blueprint for Stronger Service, USDA has taken proactive steps in recent years to reduce spending, streamline operations and cut costs. Our savings and cost avoidance results for the American taxpayer through the end of fiscal year 2014 were recently revised upward to \$1.368 billion from the previous \$1.197 billion figure reported in January 2014. I appreciate the Subcommittee's approval of authority allowing the Department to establish a non-recurring expense fund for facilities infrastructure capital acquisition. This fund will provide much needed resources in future years for USDA's infrastructure modernization.

The President is again asking Congress for authority to submit fast-track proposals to reorganize or consolidate Federal programs and agencies to reduce the size of Government or cut costs. Granted the authority, the Administration is proposing to consolidate the FSIS and the food safety components of the Food and Drug Administration to create a single new agency within the Department of Health and Human Services. The President also proposes the consolidation of certain business programs in a new department dedicated to promoting U.S. competitiveness and exports.

The Farm Bill included several reforms to the Federal crop insurance program; however, there remain further opportunities for improvements and efficiencies. The President's 2016 budget includes two proposals to reform crop insurance, which are expected to save \$16 billion over 10 years. This includes reducing subsidies for revenue insurance that insure the price at the time of harvest by 10 percentage points

and reforming prevented planting coverage, including adjustments to payment rates. These reforms will make the program less costly to the taxpayer while still maintaining a quality safety net for farmers.

I believe that the future is bright for America and in particular for rural Americans. The investments we make today are having an impact and creating a future full of opportunity. The budget presented to you will achieve the President's vision for the middle class by restoring the link between hard work and opportunity and ensure that every American has the chance to share in the benefits of economic growth. At this time, I will be glad to answer questions you may have on our budget proposals.

Secretary VILSACK. And in the interest of time, I'm prepared to take your first question.

#### DIETARY GUIDELINES

Senator MORAN. Let me start with one related to dietary guidelines, a question that you and I discussed in my office and a question that you have not had to respond to previously.

I was looking back at the history to find out what the purpose of the dietary guidelines, what's the statutory authority, what are the criteria by which those dietary guidelines are to be determined. And I have now read that, and it talks about nutritional and dietary information.

I've been most recently interested to see what Senator Dole had to say in February. Just a few days ago, he talked about being the co-author of the dietary goals for the United States with Senator McGovern and indicated his concern about the direction that the advisory committee report is heading.

These dietary guidelines, when you and I talked, you talked about how you're coloring within your lines, a phrase that I remember. And I am interested in knowing whether you have the ability to insist that others color within their lines, what conversations you've had with Secretary Burwell, and what your expectation is for the next step in the dietary guideline process.

Secretary VILSACK. Mr. Chairman, we are in a comment period right now, so we are soliciting comments from folks. I have talked briefly with Secretary Burwell, primarily about the request for an extension of time in terms of the comment period. We obviously are under a deadline to get this done before the end of the year. So we will be working with the folks at the Department of Health and Human Services (HHS) to determine what's best in terms of an extension if one is granted.

I would say that we understand, or I understand, my responsibility is to focus on diet and nutrition, and well we should, given the challenges that we face with the obesity epidemic among our children and some of the concerns of chronic diseases. I have been interested in the testimony that Commissioner Hamburg has provided in which she has indicated a desire also to stay within the statutory guidelines, to color within the lines, as you say.

And I think we understand and appreciate that folks can have many recommendations and many opinions, but at the end of the day, our decisionmaking process has to be focused on dietary nutrition, so that we can give a general guideline to American families, and that we can then inform our Federal nutrition programs.

Senator MORAN. So it is your understanding that what the goal is is dietary and nutritional guidelines, nothing more or broader.

Secretary VILSACK. That's the direction that you have given us, and that's the direction that I intend to follow.

Senator MORAN. Mr. Secretary, let me ask you then about the public comment. You mentioned that we are in the process of public comment right now, granting 45 days for those public comments. The report is 571 pages long. That's not a lot of time for stakeholders and interested parties to digest that information. Are you considering an extension of that deadline?

Secretary VILSACK. I would point out, Mr. Chairman, that that is longer than the last guidelines. I think the last time we went 30 days. We have extended it to 45 days. And I recognize that there is a lot of issues and controversy associated with this. So I would certainly be willing to consider lengthening that time. I'm not sure that we can afford to go as long as some have suggested, but it may very well be appropriate for us to extend the deadline a bit.

#### CONSERVATION TECHNICAL ASSISTANCE

Senator MORAN. Mr. Secretary, let me turn to another topic of importance in Kansas and across the country, conservation. One of the confusing things to me about the President's budget is a proposed reduction in funding of technical assistance at the Natural Resources Conservation Service (NRCS).

And even the budget states that, in terms of environmental outcomes, the funding reduction will result in lost conservation opportunities and reduce natural resources benefits. You know, it's a \$74 billion budget. Why is there a \$44 million reduction in technical assistance funding?

Secretary VILSACK. Well, the challenge in this budget, Mr. Chairman, is that 50 percent of our budget is in four areas. It is in fire suppression and forest restoration, it is in food safety, WIC, and in rental assistance. And unfortunately, in several of those four line items, we have seen increases that we believe need to be dealt with through some congressional direction and action. So we are constrained a bit by the fact that those increase.

We are also cognizant of the demands that you all placed on us relative to sequester and to make sure that we stay within a reasonable budget. This is a budget, by the way, that is less than the first full budget that I worked with in fiscal year 2010. So we are trying to be conscious.

Let me say as far as the technical assistance, it doesn't necessarily mean that less work is going to get done, and I say that for two reasons. One, because I think we are going to see significant increases in the utilization of technology that will provide us the opportunity to expand our reach in terms of conservation. And secondly, we are extending the number of partnerships that we have with a variety of other organizations and entities that can provide technical assistance as well.

So it doesn't necessarily translate to less conservation. It just simply means that we are going to be more reliant on technology and partnerships.

## CROP INSURANCE

Senator MORAN. Thank you. Let me ask about another President's budget recommendation, this one related to crop insurance. I am sure that you have heard as I have about the importance of crop insurance. When they have a conversation with the farmer, that's generally the point they would highlight about the importance and value of crop insurance to them.

We are seeing, in the President's budget recommendation, a reduction in the support levels for farmer's crop insurance premiums. I would like to have your response on that.

And then I would like to tell you that, in voting for the farm bill, one of the things I thought was most important for farmers, particularly Kansas farmers, was changes in crop insurance related to the ability to have separate enterprise units by practice, separate coverage levels by practice, and an APH yields exclusion available to take out a year of, in our case, drought.

What I discovered when I returned home after the farm bill and people started looking at the farm bill and taking a look at their crop insurance for winter wheat, elimination of that year and the other two provisions that I thought were so valuable were not available for winter wheat because of timing. And my question is, can you assure me, and I can assure my farmers, that the timing will not be a problem and that those provisions will be updated sufficient to be used as they make decisions and have the consequences of the new farm bill for winter wheat?

Secretary VILSACK. I believe so on the second question, Mr. Chairman. We are working very carefully to make sure that the 2016 crop year for winter wheat is covered under Actual Production History (APH), and we are working diligently to get the irrigated enterprise issues resolved.

As it relates to the budget, \$8.2 billion, we believe, is adequate and sufficient to cover the \$109 billion risk that is covered by crop insurance. There are two issues that I would point out.

One is on the prevented planting. The Government Accountability Office (GAO) and our own inspector general have been critical of the way in which that program has been utilized. It is discouraging the planting of a second crop, and it ends up, essentially, overcompensating folks. So in response to the GAO concerns and our own inspector general's concerns, we made adjustments, and that is part of the reason why you see a reduced amount.

The second area that I would point out, too, is on the harvest price loss aspect. Crop insurance is designed to protect against Mother Nature. The harvest price loss option basically provides coverage not just against Mother Nature, but also against market decisions that producers make. And so I think it is important to ask the question, what is the nature of the partnership between the taxpayer and the Federal Government and the farmer as it relates to that.

When you see potential premium subsidies as high as 80 percent for some farmers in some crops in that area, you have to ask yourself whether or not it's appropriate to adjust that downward a bit, which is what is reflected in the budget. So I think there are jus-

tifications for what we are proposing, but understand and appreciate that we do understand fully the importance of crop insurance.

Senator MORAN. I will follow up that would my time returns.  
Senator Merkley.

#### RURAL ENERGY SAVINGS PROGRAM

Senator MERKLEY. Thank you. Thank you, Mr. Secretary. I wanted to start by asking you about the Energy Efficiency and Conservation Loan Program. This program provides loans to rural electrical co-ops, so that they can in turn provide loans to folks for energy-saving retrofits, both residential and commercial. It has not worked real well yet, and there have only been a couple of loans made to rural electrical co-ops.

There is a program that has been authorized in the farm bill, the Rural Energy Savings Program, that is designed to try to make a more effective form of this strategy, because it's a win-win all the way around, creates a lot of jobs in rural areas, improves energy efficiency, and make homes more comfortable. Have you taken a look at this program and considered ways to improve on it and—well, I'll just stop there.

Secretary VILSACK. Yes, we have, Senator. We basically are focusing primarily on a major initiative in a State that is very interested in pursuing energy efficiency, and we are very close to getting that statewide program in place, which will, I think, significantly increase interest in the energy efficiency program.

One of the concerns, and I think you are well aware of this given your advocacy for this, is the interest rate and the fact that this is a relatively new program for the Rural Electric Cooperatives (RECs) is to implement, so it has been a learning curve, both for our folks and for the RECs. I think if we were to take a look at the interest rate, it would obviously increase the cost of the program, but it might increase the interest as well. We would continue to work with you and continue to work with Congress to make sure that we implement this in an appropriate way.

But we are focused on it, and I am asking our team at the Rural Utilities Services (RUS) to get this done.

#### POLLINATORS

Senator MERKLEY. Great. Well, I appreciate that very much. Look forward to continuing that conversation, because done right, it could be a powerful force for rural jobs. And as I head to my 36 counties every year and talk to folks in the rural counties, rural jobs would be a wonderfully welcomed item.

Let me turn then to the concern over the loss of pollinators. And as you are very aware, and folks in the agricultural community are very well, we have suffered a lot of losses of honeybee colonies. We have seen the monarch butterfly migration collapse over the last 10 years. And this is significant for agriculture, since pollinators contribute more than \$24 billion to the U.S. economy, and at least 90 of America is commercially grown crops are dependent on pollination.

So can you talk a little bit about the proposal that you're putting forward in both the Agriculture and Food Research Institute (AFRI) and the Agriculture Research Service (ARS).

Secretary VILSACK. Senator, the effort with pollinators is a complicated one, because it involves parasites, pesticides, pests, the stress of the travel that the pollinators undertake, the lack of crop diversity in some areas, so what is required is a holistic approach that involves research, and involves public education, and also involves habitat.

In all three areas, we are working, and the request in the budget would reflect a desire to do more work on the research side, to understand better the stresses, to understand better the issue of parasites and pesticides and the like, the multiple causes. And we are also working through the Natural Resources Conservation Service (NRCS) and our Conservation Reserve Program (CRP) program to expand habitat, particularly in the upper Midwestern States where 65 percent of the hives basically end up during the summer months.

The goal here is to get down from where we've been the last 10 years, roughly 29 percent of our hives being lost, to getting it closer to 18 percent, which is a sustainable level. Last year, it was 23 percent, which is good news, but it's still not good enough.

Public education is also important, and I think that's where—effort can undertake to make sure that people understand that they have a role to play here, from community gardens to the plantings that they make in their own individual personal gardens. You can create additional habitat. So it's a greater awareness, more research, and more habitat.

Senator MERKLEY. So you have proposed an increase of just over \$30 million in these activities. Is that high on your list of priorities?

Secretary VILSACK. It is certainly a significant priority, particularly as it relates to the statistics that you provided in terms of the importance of pollinators. I am particularly focused on the fact that our almond crop, which is a fairly significant crop and an export opportunity for us, is very much dependent on us getting this right. And you mentioned the monarchs, that's another issue as well.

#### RENTAL ASSISTANCE

Senator MERKLEY. Well, thank you, Mr. Secretary. I am going to switch to a different challenge which is that, over the next 3 years, about 120 multifamily housing loans will mature each year, representing over 10,000 units of affordable housing that will be exiting the program. And this problem gets even worse down the road.

In 2019, the number of maturing mortgages will exceed 1,100 and continue to increase thereafter. When these loans are paid off, the projects will no longer be in USDA's affordable housing program, and the families will not have access to rental assistance or servicing options that the Department can offer. This is a real substantial challenge for real communities seeking affordable housing and I thought I would offer you the chance to comment on the strategies to address this.

Secretary VILSACK. Well, Senator, we really appreciate you bringing this to the attention of the body. It is a critical issue. Seventy-five percent of our rental units could potentially get out of the program without access to vouchers as a result of mortgages being

paid off. We are requesting a series of tools that would allow us to manage this more effectively.

Those tools can include extending the life of an existing loan, re-amortizing that loan, using the resources potentially to improve the properties. We have also requested additional resources for new construction, which has not been the case for quite some time because of the rental assistance challenges that we face. We have also asked for a consideration of the voucher program to be available for a limited period of time as well for these expiring mortgages.

It is a serious issue, and you are absolutely correct, these people have no place to go, given their current status. So we hope to be able to work with you to get a series of tools to be able to deal with this issue and the other issue with rental assistance in terms of the ever-increasing budget challenge that we face with rental assistance.

Senator MERKLEY. Thank you very much.

Senator MORAN. Senator Merkley, thank you. Senator Cochran, the chairman of the full committee.

#### FARM SERVICE AGENCY FUNDING

Senator COCHRAN. Mr. Chairman, thank you. Welcome, Mr. Secretary, to the hearing, and thank you for the good job you do as Secretary.

One question occurs to me right off the bat here is why the administration has reduced its request for funding for people who will be used at the Department to help producers comply with provisions of the farm bill so they will be eligible for support in farm bill reforms that have occurred. There is concern, I'm told, that the President's budget request, for specific example, for the Farm Service Agency (FSA), is \$12 million below the 2015 enacted level. There is concern that we have received that this is not enough to carry out and help producers comply with farm bill provisions enacted by Congress and now must be implemented by producers and Department of Agriculture (USDA) workers around the country.

My question is, would you please look at this level of funding and let us know whether this is really adequate? Is \$12 million below the enacted level for fiscal year 2015 for the Farm Service Agency to implement and help carry out provisions of the 2014 farm bill, there is concern that the FSA appropriation, if we gave you what you're asking for, is not enough to do the job. Would you look into that and tell us what your plans are?

Secretary VILSACK. Mr. Chairman, we obviously would respect your request. I would say that one of the reasons why we are asking for a bit less is because there may not be quite as much of a need for technology money as in the past, because of the completion of the MIDAS effort. There is still an ongoing IT need, but perhaps not at the level that we have seen in the past.

Secondly, I would say that the performance of our folks at FSA offices across the country in terms of the implementation of the farm bill has been, in my view, well done, given the fact that over 600,000 disaster payments have been made by those FSA offices, given the fact that nearly 90 percent of folks have made the decision to reallocate their base acres and adjust their yields. We are

now close to 70 percent of farmers making the election of Agricultural Risk Coverage (ARC) and Price Loss Coverage (PLC), and we are not yet at the March 31 deadline. There are series of other things that our FSA folks have been doing, so I am confident that we will be able to get the job done.

But these budgets are challenging, and they are challenging in large part because of four areas that continue to increase, or several areas that continue to increase, from rental assistance, to fire suppression, to the WIC program, that places a great burden when we are trying to constrain our budget based on instructions from Congress.

Senator COCHRAN. Thank you. Thank you, Mr. Chairman.

Senator MORAN. Mr. Chairman, thank you. Senator Tester.

#### ARC/PLC SIGNUPS

Senator TESTER. Well, thank you, Mr. Chairman, and I want to thank you, Mr. Secretary, for the job that you have done over 6 years now in this position. And as a person that is directly involved in production agriculture, I just want to thank you. Thank you for what you've done. I think you've done a great job in running the agency, and I think the people you have on the ground in the Farm Service Agency, in Montana at least, are doing a great job.

The question I have to begin with is, can you tell me—you have got some deadlines coming up on PLC and ARC as of March 31. Computer programming has always been a concern. If the programming is there, when the producer walks in it can meet the needs. Can you give us a quick update on where the programming is, if it's where it needs to be?

Secretary VILSACK. Well, Senator, I think roughly 70 percent of producers that we expect have to make an election have already made the election. I think they are finding that the times can be as quick as 12 minutes through the process, in part because of the technology changes that we have made. We had an initial glitch that arose in Kansas, which we have addressed. So I think we are okay.

What we are concerned about, and producers have responded, is a crush at the end of the deadline. But given the fact that we're now at nearly 70 percent of signups in elections, I think we are going to be just fine in terms of being able to handle the volume.

#### RURAL OUTMIGRATION

Senator TESTER. Good. Good. Now, I want to go up to 30,000 feet. I've been involved and run our farm for almost 40 years now and been involved in everything from set-asides to payment in-kind (PIK) payments to direct payments to countercyclical payments. Now we've got ARC, and we've got PLC. All these programs are passed by Congress, and you are asked to administrate them. You have been doing this job, as I've said, for over 6 years.

And over the last 30 or 40 years, I have seen a mass exodus off the land. A mass exodus. The school where I went to school, 165 kids, now has less than a third of that directly associated with consolidation and agriculture. We have seen consolidation in the marketplace, not as much competition as we would like. We are seeing

consolidation in production agriculture, and I am a big supporter of family farms.

And to be honest with you, I've been a big supporter of the farm bill, too. I mean, my grandfather would have told me that we would not be on the farm we have today if it wasn't for FDR and the farm program that was out there. We wouldn't have electricity if it wasn't for that Agriculture Department in the 1930s, in the 1940s, and many of us would not have water without them. So it's done a lot of good things.

You have been in this position for a while. You have seen the impacts on the ground, and I don't think Big Sandy, Montana, is any different than any small town in Iowa as far as depopulation and the mass exodus. As you look at this farm bill, is it helping keeping people in rural America, or is it encouraging more consolidation and people to move out of rural America?

Secretary VILSACK. Senator, I think it's significant in terms of the assistance it can provide, because I think it supports a companion economy that can essentially combine with production agriculture and experts to focus on local and regional food systems and major investment in that opportunity for smaller sized operators to have a direct line with their consumer where they are able to negotiate a price. I think there is significant opportunity for expanded conservation and tying that into the development of ecosystem markets, which is another income. And then the bio economy, I think, is also—were going to bring manufacturing back to rural areas. So I think this will help.

I would say that there are two issues on the horizon that we need to be concerned about. One is this issue of the aging nature of farmers today in America and the issue of land tenure, who is going to own the land, who is going to operate the land, and what is their focus going to be in the next 10 to 15 years, because I think we are going to have a significant turnover. And then finally, just the public relations effort to acquaint people in this country of the importance of rural America and the need for continued investment and continued focus. It's easy for many in America to forget about the importance of rural America.

#### LOCAL FOOD SYSTEMS

Senator TESTER. I agree with the local food system stuff and the conservation. I want to get in that in a second. But I also think that there is plenty of room for manipulation. Farming the farm bill isn't something that is not done. It is done regularly, and I'm not sure that's input. And by the way, that's not your problem, that's Congress's problem. You are there to administer it, we set the rules, and we thank you for that.

Local food systems, can you tell me in your budget if there are additional dollars for local food systems, or has it been cut?

Secretary VILSACK. There are additional resources as a result of the farm bill, and there's additional focus in rural development on making sure that we support local and regional food systems. Just yesterday, we announced \$26 million available for—

#### CONSERVATION

Senator TESTER. Okay. Good. How about conservation?

Secretary VILSACK. Conservation increases over what was spent last year, it's not as much as would have been appropriated if we had followed the farm bill, and I'm happy to talk about that if you wish.

Senator TESTER. Well, we'll put it forth to you in writing. But I think the conservation is important. I think it's all important. It just depends on how it can be manipulated, quite frankly. And I think that the conversation that we need to have in Congress is, is the farm bill really supporting family farms, or is it supporting agribusiness? Thank you, Mr. Secretary.

Senator MORAN. Senator Tester, thank you. Senator Collins.

#### BIOENERGY PROGRAM FOR ADVANCED BIOFUELS

Senator COLLINS. Thank you, Mr. Chairman. I think Senator Tester just raised an absolutely essential issue that does deserve our attention. And before I begin my questions, I also want to associate myself with the concerns expressed by Senator Merkley about the pollinators. They are very important to our wild blueberry crop in Maine and the health of those bees, which has been a real concern in the last few years.

Mr. Secretary, I appreciate the attention that you have given to promoting the development of homegrown bio energy and wood products which are so important to rural communities across America but particularly to my State where the forest products industry is such a vital part of the economy.

I have been hearing from wood pellet fuel manufacturers in Maine who have alerted me to concerns with an interim rule that your Department has issued for the bioenergy program for advanced biofuels authorized by section 9005 of the 2014 farm bill. And I believe that Virginia Manuel, who is one of your key people in Maine, has also passed onto the Department the same kinds of concerns that she is hearing.

Wood pellets, which are recognized by USDA as advanced biofuels, represent a very efficient and use for material that otherwise is a waste byproduct. I'm told however, that the program is being implemented in a way that severely disadvantages solid based advanced biofuels, including wood pellets used in heating applications.

USDA has imposed deep discounts on the payments to solid biofuel producers, it's like an 85-percent discount, and an overall payment cap on companies in this sector, which contrasts starkly with the payments being made to liquid advanced biofuel producers used in the transportation sector. And what I am told by the pellet manufacturers is that these discounts are so steep that it's such a small amount of money that it's barely worth participating.

I don't understand what the rationale of the Department is in implementing the program in a way that is not fuel and technologically neutral. It seems to me that that should be the goal of the advanced biofuels program. I wondered if you could comment. I realize this is just an interim rule, and I am hoping that the Department will reconsider in issuing a final rule.

Secretary VILSACK. Senator, when initial proposal was put forward, we received a lot of comments from the liquid biofuel industry indicating that their belief was that it disadvantaged their in-

dustry and advantaged, unfairly, the wood pellet industry. So there was an effort in the interim rule to try to respond to those comments. The wood pellet industry didn't initially respond to that first iteration.

But I get your point, and I think you're absolutely correct that we ought to be looking for that sweet spot where we are not advantaging or disadvantaging any, but we are encouraging all. And we would be happy to continue to work with you and the folks in the wood pellet industry to find where that sweet spot is. I suspect that there will be some adjustments based on the concerns that you've expressed, but I think we are still working on trying to figure out exactly how to do it so that we get the right balance.

Senator COLLINS. Thank you very much. I can assure you that the industry is organized and aware now and weighing in, and I will make sure they've officially communicated with you. I have a letter from the Maine Pellet Fuels Association that explains the problem very clearly, which I will share with you and ask unanimous consent be included in the record as well.

Senator MORAN. Without objection, so ordered.

[The information follows:]



97A Exchange Street, Suite 305 • Portland Maine 04101  
 Phone: 207-752-1392 • Fax: 888-612-0941  
[www.maineplettheat.com](http://www.maineplettheat.com) • [feedalliance@gwi.net](mailto:feedalliance@gwi.net)

The Honorable Susan Collins  
 United States Senate  
 413 Dirksen Senate Office Building  
 Washington DC 20510

Dear Senator Collins:

We, the undersigned Maine wood pellet fuel manufacturers respectfully request your assistance in achieving a more equitable distribution of advanced biofuel producer program payments under USDA's administration of section 9005 of the 2014 Farm Bill (P.L. 113-79), the Bioenergy for Advanced Biofuels Program.

We are writing to you because of your long-standing commitment to our Maine forest products industry and particularly your advocacy on behalf of the "Power of the Pellet," as you have termed it.

The Bioenergy Program for Advanced Biofuels has played a vital role in providing modest federal support for the manufacturing of advanced biofuels used in thermal applications. During the recession, these producer payments helped many small and struggling manufacturers, including our companies, to weather stagnant markets. Today, these payments enable manufacturers to keep costs in check and maintain competitive pricing for residential and commercial consumers – many of whom are switching from expensive and price-volatile heating oil and propane to renewable advanced biofuels. As you know, Maine's heavy dependence on heating oil is a major issue for our state.

Specifically, we request that you include language in the federal FY2016 Agriculture appropriations bill directing USDA to amend regulations implementing Section 9005 to achieve a more equitable distribution of payments among and between the different advanced biofuels that qualify under the program.

Our organizations believe strongly that section 9005 should be implemented in a way that is fuel and technology neutral, without prejudice against any one energy pathway (i.e. transportation, electric, and thermal applications). It is our strong belief that payments under Section 9005 – to the extent that funds are appropriated by Congress for the program – should be made on the basis of the inherent energy content of the qualified advanced biofuel produced, regardless of whether that fuel is used in a transportation, electric generation, or thermal technology. The current 85% discount applied to solid thermal fuels and overall 5% program-wide cap on solid thermal fuel payments are arbitrary and unjustifiable on any rational, defensible grounds. The effect of these arbitrary regulations is to direct that vast majority of funds to liquid biofuel producers, while pellet fuel manufacturers receive only small and insignificant producer payments despite the significant contribution we make. Liquid biofuels already receive the \$1 per gallon biodiesel tax

credit that was recently renewed in the tax extenders bill as well as the \$1.01 per gallon tax credit in the Farm Bill. In addition, producers receive RINS qualification under the federal Renewable Fuel Standard. Pellet fuels receive no such recognition.

The Biomass Thermal Energy Council has attempted to address this issue through communication with USDA Secretary Vilsack and with senior officials at USDA for over two years. BTEC was told as recently as October 27, 2014 that USDA will not address our concerns unless they are told to do so by Congress.

Federal energy policy needs to move away from policies and programs that favor certain technologies or pathways "that pick winners and losers." Where different biomass energy pathways may compete for common feedstocks, Section 9005's current program rules strongly favor the liquid transportation fuel pathway, even though net public benefits derived from displacing fossil fuels may be equivalent or greater for a thermal, combined heat and power, or electric power pathway. The reauthorization of the 2014 Farm Bill and Section 9005 offers USDA a fresh opportunity to revisit the flawed assumptions that were the basis for implementing the current regulations.

We thank you for your consideration of this request, and look forward to working with you and your staff to arrive at the most appropriate way to achieve the objective of a more fair and equitable distribution of producer payments under section 9005 of the Farm Bill.

Sincerely,

Matthew Bell, President  
Northeast Pellets  
Ashland, Maine



Larry Carrier, Manager  
Corinth Pellets  
Corinth, Maine



Jonathan Kahn, Owner  
Geneva Wood Fuels  
Strong, Maine



Robert Linkletter, Owner  
Maine Woods Pellet Company  
Athens, Maine



#### SCHOOL EQUIPMENT GRANTS

Senator COLLINS. Mr. Chairman, I see that my time has virtually expired. I'll just raise one more issue very quickly and ask for response for the record.

Nationwide, 88 percent of schools report that they need at least one piece of kitchen equipment and over half need more significant infrastructure improvements in order to comply with the Department's guidelines for the school lunch and school breakfast program. I'm pleased that you have announced a new round of funding for State competitive equipment grants.

And I wanted you to know that Senator Heitkamp and I have introduced a bill that would actually authorize the program. I hope you will take a close look at our bill, with an eye towards endorsing

it. And for the record, I would be interested in the impact that you're seeing as you award these grants that participate in the school lunch and breakfast programs. Thank you, Mr. Chairman.  
[The information follows:]

Since 2009, USDA has provided \$185 million in kitchen equipment funding to states and schools participating in the National School Lunch and School Breakfast Programs. USDA provides the funding to states, which then competitively award grants to school districts in order to purchase necessary equipment.

State agencies participating in the National School Lunch and School Breakfast Programs were directed to target equipment assistance grants to low income school districts via a competitive grant process, giving priority to high need schools, including schools in underserved areas, schools with limited access to other resources, the age of current food service equipment, and where 50 percent or more of the enrolled students are eligible for free or reduced price meals. In addition, school districts were required to give priority to schools that did not receive previous equipment assistance grant awards.

Based in large part on previous experience with equipment grants and on-going discussions with States and school districts, equipment funding has provided opportunities for purchasing new, energy efficient equipment facilitating the production of healthier, more attractive and tasty food for students. According to a report released by Kids' Safe and Healthful Foods Project (Pew Charitable Trusts/Robert Wood Johnson Foundation), most school districts in the United States (88 percent) need at least one additional piece of kitchen equipment to serve healthier school meals that meet the updated, science-based nutrition standards. Therefore, the President's Budget request for fiscal year 2016 includes \$35 million to provide needed funding for schools to upgrade equipment to help support nutritious meals, better ensure food safety, improve energy efficiency in the cafeteria, and expand participation in school nutrition programs.

Senator MORAN. Senator Collins, thank you very much. Senator Udall.

#### WATER INFRASTRUCTURE

Senator UDALL. Thank you, Chairman Moran. And let me echo also, Secretary Vilsack, what was said about you. I think you have done an excellent job as Ag Secretary. I think sticking in there for 6 years really makes the difference as a cabinet secretary, because by doing that, you really learn the Department, and you learn the problems, and then you focus on them and work with us to come up with solutions.

I also just want to echo what others have said about family farms. I think if you go back to the history of the farm bill, the idea was helping family farms, and I think we could do a lot more there. I see in my State a younger people going back and doing small farming, and if we could try to work with the farm bill to give them the support to stay there, I think that would be a welcome thing to happen.

But let me ask you a little bit about water infrastructure, Secretary Vilsack. Come from a State where water infrastructure is a top priority in almost every community, it's critically important that we have strong support for water and wastewater disposal grant programs and the additional resources to provide technical assistance, which is the real issue, as you know in some communities that have no ability to do technical assistance, and make sure that those grants go to the communities with the most need.

We currently have many low-income communities near the United States-Mexico border, known as colonias, that have an urgent need for water infrastructure, no way to pay for their water infrastructure needs, and are left to find the funding. And accord-

ing to a recent GAO report, the cost of replacing critical infrastructure in rural communities like these is estimated to be more than \$140 billion in coming decades.

USDA is not the only agency that provides funding and technical assistance to rural communities for water infrastructure. Can you tell me about your interagency cooperation to ensure that these rural communities are being served with an all hands on deck effort by the Federal Government?

Secretary VILSACK. Senator, I say, first of all, our budget would support 1,300 water projects in terms of wastewater and water treatment, and that would bring to a total of, I think, in excess of 8,000 projects that we funded in the time that I've been secretary. Secondly, we do work with sister agencies, Environmental Protection Agency (EPA) and others, to make sure that we coordinate our resources and we're using them most efficiently.

And third, we are now encouraging the private sector to get engaged and involved in investing in these infrastructure projects. The challenge is that in order to get capital markets interested, we need to figure out how to bundle these projects. They're not interested in funding a \$2 million or \$3 million project in New Mexico, but they would be very interested in funding 100 projects around the country.

And so we are now in the process of working with the Treasury Department and others to try to figure out how we could potentially bundle. We've had an assessment of our own portfolio to determine what the strengths and weaknesses of that would be. So we are trying to look at all areas to try to increase investment.

Senator UDALL. Secretary Vilsack, you believe the USDA has adequate resources to provide technical assistance to these communities with the most need?

Secretary VILSACK. You asked me if I have adequate resources. I suppose I should answer no. But let me just say this. Whatever you all deem as appropriate, we will try to use in the most efficient and effective way to reach as many people as possible. That is why we're reaching out to the private sector. It's why we've also worked with CoBank to create a \$10 billion infrastructure fund so that we can figure out ways, if we can't say yes, we've got somebody else who can.

I know that we can support 1,300 projects based on the budget that we submitted, and I think we have the adequate staff to be able to do that.

#### COLONIAS COMMUNITIES

Senator UDALL. Yeah, thank you. And we want to work with you on that. I know my time's running out, a quick question. We have two communities in southern New Mexico that are designated colonias, called Chaparral and Sunland Park. They have high poverty rates, limited public sector funding, and many miles from the New Mexico city of Las Cruces, but they are close to the city of El Paso, but they don't get any help.

And so these communities need rural development funds for critical housing projects and infrastructure improvements. Would you work with me to ensure these two communities do not fall through

the cracks by granting a waiver making them eligible for rural development assistance?

Secretary VILSACK. At this point in time, not sure I have the permission from Congress to do that, but I would be happy to work with folks to try to create as much assistance and help. And if we can't provide help, then maybe we can steer them to an agency or entity that can.

Senator UDALL. Okay. Thank you very much. Appreciate it.

Senator MORAN. Senator Udall, thank you. Senator Daines.

#### PORT OF VANCOUVER GRAIN INSPECTIONS

Senator DAINES. Thank you, Mr. Chairman. Thank you, Mr. Secretary, for being here this morning.

Last summer, the USDA failed to conduct federally mandated grain inspections at the Port of Vancouver, the west coast's largest grain terminal, for several weeks to the safety concerns, the result of an ongoing labor dispute. And it was over a month that tens of millions of dollars of wheat harvest were put at risk.

I remember driving in my pickup across Montana, stopping in Great Falls, our family roots are north of Great Falls, there in the Conrad area, they were wheat farmers, homesteaders, where you've got farmers coming off of their combines to meet with me, desperate, looking what's going on with the back up going on out at the port.

And I don't think anybody disputed the need for the Secretary to have discretion in case of emergency, but it took the USDA 5 weeks, until after the safety concerns were resolved, to provide these following mitigations. There was a crosswalk removed, some Jersey barriers installed, backup power sources for surveillance video, additional parking spots, some temporary inspectors. And to me, it's unacceptable. It took 5 weeks to produce the simple and low-cost mitigations, all the while the livelihoods of grain growers in Montana, across much of the West, were threatened.

As you know, the United Grain Company and others offer to provide extensive mitigations during this disruption in inspections, including several of these USDA ultimately put forward. So considering UGC's willingness to address any safety concerns, could Montana grain have been exported sooner if USDA's analysis was completed more promptly?

Secretary VILSACK. Senator, I would like an opportunity to delve more deeply into your question to be able to respond to it accurately. I was not under the impression that there was a significant delay. There was some uncertainty as to precisely who was going to inspect the grain and how safe the circumstances and conditions were.

But I would be more than happy to take a look at this to determine whether or not it negatively impacted and affected your producers. Obviously, that would be the intent.

Senator DAINES. Well, I'd be happy to get our farmers together here and chat, because it was a great concern as we're looking at backing up here and not seeing an end as the port we shut down for 5 weeks. And back in November 2013, 8 months before the inspections were interrupted in July 2014, there were several members of Congress, including myself, who urged the Department to

be prepared and have an executable plan in place that can be implemented immediately to ensure the inspections were not interrupted. And that was in direct reference to the labor dispute and the situation occurring at the port of Vancouver.

So we were just curious why they were not these plans put in place when this disruption of inspections occurred.

Secretary VILSACK. Well, I think there are plans that are in place. The challenge, though, is knowing precisely what is happening on the ground at that particular time, which is why there had to be a safety assessment to determine precisely what needed to be done to protect our people. And there are a variety of other options that were being looked at and examined relative to patrols and law enforcement involvement as well. So that's why I would like to be able to refresh my memory specifically as it relates to that particular circumstance.

#### SAFETY REPORTS

Senator DAINES. Sure. What I think would helpful is I know some of my Montana producers have expressed concerns that the Department simply played out the clock by not identifying the mitigations until after the labor dispute was resolved.

And I guess in the interest of transparency and to help address these concerns, I'd like to put this to bed. I'd ask if you'd release the three safety reports that were conducted during the duration of the lockout, and am happy to do that in a non-public setting, if necessary. Would you be willing to release those reports?

Secretary VILSACK. I don't know what the rules and regulations are relative to the safety reports, Senator, so I don't want to run afoul of any technical regulation, but I would be more than happy to have an opportunity to talk to my staff and see whether there is any objection. If there's not, I'd be more than happy to provide them to you.

Senator DAINES. I'd be happy to see those reports. And I think it's relevant. To me, it's relevant to grain growers across Montana that the USDA's decisions are transparent and held to account, and I would ask you to release those reports for review as soon as possible.

Secretary VILSACK. If I can, Senator, I'd be glad to cooperate with you. I just do not want to make a commitment to you, because I don't know what the rules and regulations are relative to disclosing these reports, if there's some security reason or some reason we can't do it by statute or by regulation. But if there's not, I'm more than happy to get those to you.

[The information follows:]

USDA acknowledges the interest in having the safety reports available for the sake of transparency. For this reason, USDA would be glad to meet with Members of Congress to go through the reports. Unfortunately, we would not be able to make the safety reports publically available as those groups that wish to disrupt operations could use the information in the reports to contravene the measures outlined in the reports. To make the reports publically available would be inconsistent with Departmental Regulation 3440-2.

Regarding the impact on producers by the lockout at the United Grain Corporation of Vancouver, Washington, the views of your constituents are very important to us. If you have producers that are willing to share contracts that were invalidated as a result of the shutdown or some demonstration of harm, we would welcome the information.

Senator DAINES. I think it's important to remember that we're here to serve the people, not the other way around. Having transparency in that process, particularly with the Montana farmers were gravely concerned about getting their products to port, I think it would help restore the trust, because I think it, frankly, has broken down. Mr. Chairman, out of time.

Senator MORAN. Senator Daines, thank you very much. Senator Blunt.

#### WATERS OF THE U.S. RULE

Senator BLUNT. Thank you, Chairman. And Secretary, it's great to see you here. And I want to join others who have said how much we appreciate the 6 years now that you've served in the job, and I continue to see the Department benefit, and I think Missouri and American agriculture benefit by your leadership.

One of the things that I continue to hear about probably most from local officials, ag interests, is the EPA's proposed waters of the U.S. rulemaking, the interagency part of that involves you in a significant way. I've got about three things I want to get you here, I don't want this to become a 4-minute answer, but a sense of where you are on your comments to EPA as they've got that proposal out there and the impact that you think it might have on U.S. agriculture.

Secretary VILSACK. Well, Senator, I think we have been very specific with EPA, expressing concerns about some of the definitions and the clarity of those definitions, especially as it relates to ephemeral streams, is it a river, is it a bank, is it a bed, is it a constant flow. And I think administrator McCarthy's comments yesterday to the National Farmers Union reflected an awareness of that concern when she acknowledged that perhaps things could've been done a little bit better in terms of rolling this out and that there are likely going to be changes based on what she has heard from us and from the countryside.

#### BIG DATA

Senator BLUNT. Well, keep talking, because I think the idea that somehow any water that can run into any water that can run into any water that could be navigable meets the standards of the Clean Water Act is a real problem.

On another area that I wonder what you're doing on is the aircraft drone, aircraft system for drones. Many of our farmers think there is a lot of potential here. They want to be sure, of course, that the drones that give them advantages they wouldn't otherwise have don't become aerial ways to look at things on a farm that the government would otherwise have to go to court and asked to come and see.

What's your advice on how these drones can best be used and how that rulemaking should go about?

Secretary VILSACK. Well, I think the Federal Communications Commission (FCC) is doing a pretty good job of trying to figure out precisely where the sweet spot is relative to getting the information and maintaining the secrecy or privacy of the information. Frankly, our focus has been on sort of a larger piece, which the drone is part of, which is this whole issue of big data, where we been working

with the businesses, and the companies, and the farm organizations, and the Farm Bureau in particular, to make sure that there is an understanding of the need for tight firewalls to ensure that someone's information is not inappropriately used or inappropriately disclosed.

The big data is important for us, because it really does create the opportunity for us to do a better job of research, a better job of understanding the condition of soil, the better job of using inputs more efficiently and effectively, all of which will help the bottom line for producers. But I know that producers are a bit concerned about whether or not this is going to be used to regulate them. I don't think that's the intent.

#### MIDAS PROGRAM

Senator BLUNT. Well, I would hope not, and I hope you continue to make that case on the privacy issues. Certainly, if any endeavor leads to someone's sense of individualism, in our country, it's always been American agriculture, and the decision of what you do and how you do it is better informed by lots of information, but you and I both know that farmers and farm families want that information to be tightly held. And it can be used in a good way, and you continue to advocate for that and understand where those privacy walls are very important.

On another topic, Secretary, we talked several times over the last 2 years about where the Department was with the MIDAS program, which has been discouraging for me and probably for you. I think the original estimate was it would cost about \$305 million and be completed by March of last year. Last count I heard, we were over \$400 million. And the GAO recently said that it is on the high-risk list of programs as to whether we get there or not. Where do you think we are on this program?

Secretary VILSACK. We're in a better place today than we were when this began. Unfortunately, there was not a consensus in the offices in Kansas City and the offices in DC in terms of where the focus should be, whether should it be on farm records, whether it should be on integrity. There was a mismatch of vision. I think there was a lack of a project manager.

We now have a—MIDAS is basically now completed. The farm records is in place. The integrity, business integrity, stuff is in place. We have a project manager. We incrementally tested the business integrity part of it effectively. We are now in the process of developing, for this year, the acreage reporting, and we are going to do this in a very systematic, focused way. There's a project manager for that job. It's very tightly defined.

The question will be whether or not we use existing software and hardware, or whether we are required to do something beyond that, but we are going to make an informed decision. We are not going to jump into it. And when we implement, we're going to implement it in stages so that we are confident that it's actually going to do the job it is intended to do.

So I think we're a much better place, but I will be the first to admit that we didn't do as good a job on this as we should have.

## ELECTRONIC ACCESS TO RECORDS

Senator BLUNT. Thirty more seconds, Mr. Chairman. On this topic, last year at the same hearing you said that you thought that, by sometime in 2015, farmers would be able to be at their kitchen table and look at records and FSA programs. I assume we no longer think that's possible.

Secretary VILSACK. Well, it's possible, but I don't want to over commit. I think that we want to do this systematically and thoughtfully. We are working on two separate issues here. We are working on the farm service piece of this. We are also working on the Natural Resources Conservation Service (NRCS). And what we've discovered in our NRCS efforts is that we can use that as a gateway for the farm service that will potentially save money and save time, so we are in the process of interfacing those two efforts.

We're going to get there, Senator. And I think we've already created a much more convenient effort, and that's one of the reasons why we been able to move through the farm bill implementation as quickly as we have, because farmers can go into one office, access all records of all land that they own, regardless of where it's located. That's a significant convenience. And we're also able to access records quickly so we're going to significantly reduce mistakes, and it has really streamlined the process.

So there has been benefit, and this year will be another forward, if you will.

Senator BLUNT. Unless we get another question in here today, will have a couple of more questions on that for the record. Thank you, Mr. Chairman.

## AVIAN INFLUENZA

Senator MORAN. Mr. Chairman, thank you. I think our intention is short in the second set of questions, try to be done by the end of the first vote, and then we wouldn't come back.

Let me ask a question related to the avian influenza. It has been detected. It is in several States, including some represented here on this panel today. I'd like to hear what the Department is doing to combat avian influenza and its spread. It appears to me that the only commercial detection has been in turkey flocks, but we have countries who are banning chicken, poultry, chicken products as well as turkey, and is there something that can be done to narrow the scope of any trade disruption?

And then Dr. Johansson might be able to answer this question in response. I wanted to give him a chance, in case it's important for you to be able to say that you actually testified before a Senate committee. But a K-State agricultural economist, Dr. Glynn Tonsor, indicated that this may have consequences for other livestock producers and pricing within the livestock sector. As people make decisions, exports decline, prices change, is there something for the beef side that has a consequence to avian flu as well?

Secretary VILSACK. Senator, this is a very complicated set of circumstances here. Fifty-eight incidences have occurred. I think it's in 11 or 12 States in several of the flyways. It is in both chicken and turkey. It is in both commercial enterprises and sort of individual farming operations.

The Animal and Plant Health Inspection Service (APHIS) has a responsibility to work with States to identify, as quickly as possible, the fact that there is AI and what type of AI it is, we're seeing several different types, and then work with the States to impact and affect biological controls to try to contain the spread of this within a flock, within a particular area, and then to indemnify the producers for any loss that they've incurred. And that's ongoing today. We are going to go to the resources that are budgeted for that, and if necessary, if we need additional resources, we have the CCC that we can trigger.

As far as it relates to exports, there are three classifications of countries. There are 11 or 12 countries, I think, that have basically banned all poultry, regardless of where it comes from, in the United States. There are somewhere in the neighborhood of 33, 34 countries that have essentially regionalized their bans based on where this is actually occurred, which is more consistent with the World Organization for Animal Health (OIE) guidelines. And there are a variety of States and countries that don't do a lot of business with us that have not instituted a ban of any kind.

We've focused our attention on those countries that have created an all ban to try to encourage them to take a more reasoned approach and look at this from a regional perspective. That obviously requires them to be reasonable, which, in some cases, is not easy to attain. But we are educating them through communication with their embassies, communication with the ag secretaries and commissioners and my counterparts, if you will, letters, efforts and phone calls, some of which, frankly, have not—some phone calls have actually been refused, which is unfortunate.

But we are trying to put folks on notice that the most appropriate way is to regionalize this. This represents roughly 14 percent or so of exports at this point in time, but its impact on markets, I think, Dr. Johansson can elaborate, but we are focused on this. There is no cure for this. It's essentially the identification, containment, and indemnification, and trying to limit the impact from an export basis.

#### OIE STANDARDS

Senator MORAN. Mr. Secretary, is it clear that those countries in the first category, the ones you're now dealing with, is it clear that they are violating the OIE standards?

Secretary VILSACK. It is clear to us that they—yes, it's clear to us that they ought to be regionalizing their bans and not doing a blanket ban, but this is not unusual. This happens from time to time. We have been working with several of our trading partners for an extended period of time on bans that are still in place from incidents that occurred many, many, many years ago. And in some cases, they've banned States that aren't even connected in any way, shape, or form to an AI incident.

#### DISRUPTION IN POULTRY TRADE

Senator MORAN. Dr. Johansson, to my knowledge, the only time I've ever been rude, and this was unintentional, was to Joe Glauber, your predecessor, when he was a witness and I was a House

member, and so I want to demonstrate that I can get along with the ag economist at USDA.

Dr. JOHANSSON. Well, that's very kind of you. I'm sure that Dr. Glauber would remember that exchange fondly, as you do.

Dr. Tonsor is, I think, referring to the fact that, if we do see significant disruption in poultry trade that that would potentially lead to lower price poultry products in the United States and perhaps consumer, which we've seen this trend occurring over time, the movement toward increasing consumption of poultry in the United States relative to beef, and that's due to a number of factors. Beef prices right now are extremely high. But as the Secretary pointed out, we're working with our trading partners right now, and right at this point in time, that doesn't seem to be an issue. We seem to be able to ensure access of our poultry products, turkey and chicken, to our external trading partners for the most part.

And if some countries do make that more difficult, then we have other outlets for those goods. So right now, I wouldn't expect there to be a significant impact on the beef sector from this current situation with the high path avian influenza.

Senator MORAN. That's good to hear. And Mr. Secretary, please let us know how we can help, either resources or encouraging countries to comply with those OIE standards. Senator Merkley.

#### SELF-HELP HOUSING PROGRAM

Senator MERKLEY. Well, thank you very much. I'm going to try to quickly touch on five topics in 5 minutes. Self-help housing program that involves sweat equity housing, empowerment through homeownership, pretty popular program. You suggested cutting it from \$27 million to \$10 million. Why?

Secretary VILSACK. Help us fix the rental assistance account, Senator. We basically are faced by a dilemma created by Congress. When rental assistance first came into being, you all funded these rental units for the life of the unit. Then budget constraints required you to lessen the amount of time, so now we are in the process of having 20-, 15-, 10-year projects coming on line, having to again finance them, which puts a constraint on the budget. So you've got a trade off.

If we solve the rental assistance problem, then that would free up resources in rural development to do self-help. It's not an indication of the lack of importance of that program. It's just budget numbers.

#### INNOVATION INSTITUTE FOR CELLULOSIC NANO-MATERIALS

Senator MERKLEY. Switching gears, I want to much follow-up here, given the shortage of time. But you proposed funding in innovation institute in cellulosic nano-materials. Anything involving wood, cellulose, is of interest in my State. The conversation is about potential materials that are flexible and stronger than Kevlar. A comment?

Secretary VILSACK. We do research at the forest product lab, but this would allow us to create an entity that would not be run by the Department of Agriculture, but would be implemented by the Department of Agriculture, modeled after a similar innovations institute in Berkeley on energy.

We think nanotechnology creates enormous opportunities for us, not only in the wood area but in the plant area as well, to create new manufacturing jobs and to create a new bio economy within rural America. We'd like to have this institute set up so that, in turn, we could have greater and more quick technology transfer, getting ideas.

And what these institutes basically do is they help small businesses that could otherwise not have the capital to ramp up to be able to ramp up more quickly, which means it gets the product into the commerce more quickly, creates jobs more quickly.

#### SUMMER FEEDING PROGRAM

Senator MERKLEY. I visited that laboratory in Berkeley a number of years ago. Fascinating work that's being done there.

Turning to summer lunch programs for children. Last year, the subcommittee provided \$60 million for that summer program. Can you update us on how that's working in terms of assistance for child nutrition?

Secretary VILSACK. Certainly an important component of our summer feeding program. We've increased the number of sites, sponsors, and meals, 23 million more meals being served across the program. And one of the strategies is to provide additional resources to families that may not have the access to a congregated site. We did this in 10 States. Eight of the 10 are re-upping. We think that we learned from that that in remote rural areas in particular, this is an effective way to expand our summer feeding effort.

The reality is that we've got 21 million kids in free and reduced lunch in the country, and we were able to feed 3.3 million in our summer feeding program, so there's still quite a delta there, and this is the way we think that can allow us greater tools and more flexibility to reach more kids.

#### PUBLIC LAW 480, TITLE I

Senator MERKLEY. Thank you. Public Law 480, title I, there hasn't been any new loans since 2006. In the long-term, a lot of these loans are eventually forgiven. We're still administering the old loans. Is there an effort to analyze the 255 outstanding loans and determine whether some of them should just be forgiven and reduce administrative overhead?

Secretary VILSACK. It's a good point, Senator, and I appreciate your raising the question. I would say that we are collecting somewhere between \$250 million to \$300 million a year, which is one of the reasons why we need some administrative resources.

But I think your point is well taken. And by virtue of this question, I'm going to go back and ask. We looked at our portfolio in other areas. This is a good question to ask.

#### MOBILE SLAUGHTER FACILITIES

Senator MERKLEY. And finally, let me turn to mobile slaughter facilities. And many of my rural counties, I hear a lot about the difficulty of shipping livestock of various types to a slaughter facility.

Can we get your cooperation in exploring the potential expansion and support for mobile slaughter facilities?

Secretary VILSACK. Absolutely. We're very consistently supportive of mobile slaughter units as a vehicle for increasing local and regional food systems.

Senator MERKLEY. We have 20 seconds left. Thank you.

Senator MORAN. Well done, Senator Merkley. Senator Cochran.

#### YAZOO RIVER BASIN

Senator COCHRAN. Mr. Chairman, thank you very much. Mr. Secretary, we appreciate your leadership, and we know you've got a lot of jurisdictional area that's affected by the appropriations bill that this subcommittee has an opportunity to influence. And specific programs that are in need of funding that somehow, year in and year out, come up for review, and people say, well, if we just had some more money. Well, the good news is, that we got some more money.

We have money that is available and can be spent and is authorized for funding in the Yazoo River basin in Mississippi. And I bring this specific area of the State to the attention of the subcommittee and the Secretary because it is a fertile area for agriculture. The Yazoo River basin is the largest drainage basin in Mississippi. It covers more than 13,000 square miles and 30 counties. So it is a big deal.

And the management and conservation and thoughtful use of these lands in this Yazoo River basin are important to our national economy and certainly to the economies in the States of the lower Yazoo River basin. So I invite your attention to opportunities to use funding that, and heaven help us, is earmarked, hello, for certain areas of the country. This is one of those high-priority areas, and it would be almost sinful not to provide funding for this particularly stressed area, which has not been supported by appropriated dollars through specific designation.

So I hope that the subcommittee will support providing some suggestions and directions for how these funds could be used in the Yazoo River basin. Our State has \$45 million in unfunded authorized water projects under this program, and I hope that we can see the Department looking into the situation, and if possible, carrying out the intentions as expressed by the Congress with respect to appropriated dollars for these activities.

Senator MORAN. Mr. Secretary, before you respond, the vote has been called. We're going to try to finish all questions before the vote and not come back. So if everyone can be very brief between now and the next 5, 6, 7 minutes, that would be a great experience. Mr. Secretary.

Secretary VILSACK. Fifteen seconds. Mr. Chairman, basically, I would suggest two things. One, the Regional Conservation Partnership Program is a great opportunity for that area to apply for resources. And secondly, this budget does contain \$200 million in watershed resources. Obviously, we work to figure out if that's appropriated by Congress to spend it wisely.

Senator COCHRAN. Thank you very much, Mr. Secretary.

Senator MORAN. Mr. Chairman, thank you very much. The Senator from North Dakota, Senator Blunt has agreed to allow his

time to go to you, and so you owe him an expression of appreciation, but don't do it right now, we don't have time.

#### SCHOOL MEAL STANDARDS

Senator HOEVEN. I'd like to thank the outstanding Senator from Missouri, and also you, Mr. Chairman. Thanks for being here, Mr. Secretary.

First question goes to the nutrition standards. We're going to be reauthorizing the dietary guidelines. On sodium, schools are having—you know, I mean, they're meeting the target one, and they feel that was a reduction, that it works for them. But as you know, we included in the ag approps legislation last year not going to the target two and three until additional study has been done. Has additional study been done, and what's your view on that?

Secretary VILSACK. There have been additional studies, and I think there is a game plan that provides for an extended period of time before phase two and phase 3 would be implemented.

Senator HOEVEN. So I have introduced, or I will be introducing legislation that addresses the sodium piece, and I'd be willing to work with you on it. I'm trying to come up with something that the School Nutrition Association supports based on what works for them and also something that you may feel works as well. But they are concerned about going to that target two level and being able to meet it.

Secretary VILSACK. We obviously want to provide flexibility where it's appropriate, Senator.

Senator HOEVEN. Same thing on the whole grains requirement. The 100-percent requirement is problematic for them with some products and then some flexibility and discretion there. So again, my legislation will address both, but would certainly be willing to have a dialogue on what we can do in terms of working with you on that.

Secretary VILSACK. Well, we had provided flexibility on whole grain, understanding the challenges of the food processing industry. And again, we've been willing to provide flexibility where we think it's appropriate. We are concerned, Senator, about taking a step back. We don't want to do that. We think we're on the right track. We think we are headed in the right direction. We just don't want to take a step back.

Senator HOEVEN. Well, and I understand that. But we are going to be doing reauthorization this year, so we are going to, obviously, be reauthorizing the program. It's a logical time to look at that and then determine what certainty we can give the schools in terms of handling those two issues with your recognition that they need some help on both of them.

Is there a point person in your shop we should be talking to you on this issue?

Secretary VILSACK. Me.

#### BUDGET SAVINGS

Senator HOEVEN. Great. Thank you. One other question. Where do you see—as we work to the budget process and have to find some savings, give me your thoughts on where we do that.

Secretary VILSACK. Well, actually, my thought was that you need to be careful about the application of sequester on both the defense and nondefense segments, so I am not sure on the right person to ask that question.

I would point out, Senator, that this budget that we have submitted is less than the first full budget that we submitted in fiscal year 2010 and not too far from where we were in 2009. We, I think, have done a good job at USDA of trying to manage on limited resources without a lot of growth in our budget.

Secondly, we've got those four line items, several of which are going to increase. Fire suppression, that's got to get fixed. That's got to get fixed. Rental assistance has got to get fixed. Otherwise we're going to continue to see an erosion of all the other programs that you folks think are important and that we think are important.

Senator HOEVEN. Well, and I feel like we've worked hard to find savings in the farm bill that we passed last year and that ag has stepped up and been part of reforms and savings. And I think we'll be called on to do more, but I also want to note that we've worked hard to find real savings from agriculture and still produce a good farm bill and have farmers and ranchers out there that are producing the highest quality, lowest cost food supply in the world. Thank you, Mr. Chairman.

Senator MORAN. Thank you very much, Senator Hoeven. Mr. Secretary, thank you. You were saved by the bell, in a sense. We, I think, have had a satisfactory opportunity to ask you questions. I hope this hearing is not just a benefit to us. I hope it's a benefit to you to see what we are hearing and thinking from across the country, what are farmers, ranchers, or consumers are telling us. And we appreciate your testimony and your service. I think it's been a good hearing.

#### ADDITIONAL COMMITTEE QUESTIONS

For members of the subcommittee, any additional questions that you'd like to submit for the record should be turned into the subcommittee staff within 1 week, which is Tuesday, March 24. We appreciated if the Department could respond from USDA—a response from USDA within 4 weeks from that date.

And Mr. Secretary, on the two issues you mentioned, fire suppression and housing, if there's something that we need to know to help solve that problem, please make certain we do, or other issues that need our attention.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

#### QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

##### CUBA

*Question.* Secretary Vilsack, I have been an advocate of lifting the economic embargo against Cuba for the past 15 years, and I am encouraged by the newfound momentum since the President's announcement in December. I recognize there is still a lot to be done to restore diplomatic relations, but the potential for US agricultural exports to Cuba is undeniably significant. U.S. wheat farmers believe they can supply two-thirds of the wheat Cuba is already importing from other countries.

Has USDA begun work to identify potential market access?

*Answer.* Although USDA does not have an on-the-ground presence in Cuba to assess the market firsthand, USDA's Foreign Agricultural Service monitors trade data on Cuba's agricultural imports that provides insight into the potential of the Cuban market.

If the embargo is removed, the United States could be poised to become a major agricultural trading partner with Cuba. Cuba depends on imports to feed its 11 million citizens. According to the World Food Program, Cuba imports about 80 percent of its food, which means the potential demand for U.S. products is significant. The United States has potentially huge advantages in exporting to Cuba, including lower shipping costs and transit times, especially compared to our current top competitors—Brazil and Europe.

In fiscal year (FY) 2008, U.S. agricultural exports to Cuba reached \$658 million. However, by the end of last fiscal year, they had fallen to \$300 million. At the same time, global agricultural exports to Cuba have doubled over the past decade to approximately \$2 billion. In fiscal year 2014, the largest U.S. agricultural export to Cuba was poultry, followed by soybean meal, soybeans, and corn.

U.S. agricultural exporters can capture the market in Cuba, but there are factors to be considered. Cuba is a country with limited foreign exchange. The United States is also behind foreign competitors in market development. USDA remains prohibited from providing export assistance and credit or guarantees for exports to Cuba. These restrictions in law apply to USDA's successful market development programs like the Market Access Program and the Foreign Market Development program. Another factor is Cuba's import policy requiring all U.S. agricultural imports be channeled through one state corporation, called Alimport.

*Question.* Since the U.S. government has had no formal relationship with Cuba for several decades, is there a lack of agricultural data available to accurately assess their markets?

*Answer.* Cuba last reported its trade data to the United Nations in 2006. In order to conduct more current trade analysis on the Cuban market USDA relies on export data to Cuba as reported by other countries to assess the dynamics of Cuba's import market. While direct and consistent import data from Cuba would be a preferable option, the use of export data to Cuba serves as good proxy to understand how trade patterns are changing in the country. However, there is very limited information available regarding Cuba's production and consumption trends. Elsewhere, FAS utilizes its network of overseas offices coupled with on-site assessments by Washington-based staff to gather comprehensive market intelligence. This type of comprehensive assessment has not been an option in Cuba. As the United States begins the process of re-establishing diplomatic relations with Cuba, including the opening of an Embassy, USDA is prepared with the expertise to provide on-the-ground assessments.

#### IT MODERNIZATION

*Question.* Secretary Vilsack, one issue that has been raised repeatedly by this subcommittee in recent years is the IT modernization effort at the Farm Service Agency. Despite significant investments by Congress spanning several fiscal years, the MIDAS project as we understand it has been abandoned. Your budget indicates that FSA is conducting a Business Strategy and IT Strategy to establish new objectives to seemingly replace MIDAS. What is the status of those efforts?

*Answer.* MIDAS has not been abandoned nor are there any plans to replace MIDAS. MIDAS remains at the core of the FSA IT modernization strategy. With any IT modernization effort there comes a time when the project must transition from the "development" stage to the "sustainment" stage. With the successful delivery of Product Master, Farm Records, and Business Partner, the MIDAS system has moved into sustainment. During sustainment MIDAS will receive incremental improvements to the deployed functionality and, in order to keep it operational for field office staff, ongoing maintenance of processes and technical infrastructure, including defect resolution and minor adjustments to maintain continuity with program business rules. Following the Business Partner release in December 2014, the U.S. Department of Agriculture (USDA) Executive Information Technology Investment Review Board recommended that additional functionality, such as the ability of agricultural producers to interact with FSA online, be developed separately in smaller, more modular, investments that reflect the current vision for FSA's role and opportunities to improve service, including provisions of the 2014 Farm Bill.

The FSA Farm Programs IT Plan for Expenditure that will be submitted in the coming weeks will provide details on the Farm Programs IT investments for fiscal year 2015. FSA Executive Leadership, in coordination with the Office of the Chief Information Officer, continues to leverage the Business Strategy, IT Strategy, and

Roadmap to refine IT investment plans for fiscal year 2016. A non-USDA independent third-party will be engaged to conduct an analysis of the enterprise solution to determine if the current enterprise solution provides the necessary functionality and identify a proposed strategic direction for modernizing and ensuring the most cost-effective means for delivery of IT Services in FSA's dynamic program environment. The results of this third-party analysis will be used to guide the development of additional capabilities for the current MIDAS system.

*Question.* While these IT challenges are ongoing for FSA, producers will soon be enrolling in the new Farm Bill commodity programs. Can the system currently in place handle the workload in a timely manner?

*Answer.* Following the deployment of MIDAS Business Partner capabilities in December 2014, one performance-related issue was reported and resolved. USDA recognizes modernization of the current national telecommunications architecture is required to further improve performance and enable efficient delivery of program services to farmers, land owners, and agricultural partners. In March 2015, the Service Center Agencies (FSA, RD, and NRCS) approved the USDA Client Technology Services plan to upgrade 1,035 offices. These sites were determined as most critical based upon bandwidth saturation thresholds coupled with site populations and customer traffic demands. In fiscal year 2015, 300 sites are being upgraded with an additional 735 Service Center Agency sites planned in fiscal year 2016. Sites that have been upgraded will be consistently monitored to ensure that the initial upgrade is sufficient to support the customer's changing application and data requirements. Sites not upgraded in the initial phase will be evaluated on a continuous basis to determine if saturation thresholds have changed based on new demands.

*Question.* Can producers rely on the security of the system to protect their financial information?

*Answer.* Producers can rely on the security of the system to protect their financial information. The USDA and FSA provides several layers of information security by implementing physical, network/server, application and business process security controls. Security controls are compliant with the Office of Management and Budget, the National Institute of Standards and Technology and USDA requirements for systems that process individual's personal and financial information.

#### IMPLEMENTATION OF NEW METHODS OF POULTRY SLAUGHTER INSPECTION

*Question.* Where exactly do you stand now regarding implementation of the modernized poultry slaughter program? Will implementation be completed during fiscal year 2016?

*Answer.* The implementation of the New Poultry Inspection System (NPIS) is moving forward as expected with 40–50 eligible plants expressing an interest in converting to the new system. Agency officials and union representatives are in ongoing negotiations at the present time. Full implementation is expected to be completed over a 5 year period.

*Question.* I understand that adopting these new methods is at the discretion of the plants. What is the level of interest in participation that you are seeing from the industry?

*Answer.* The level of interest we are seeing from plants is what we had predicted. At present, FSIS has between 40–50 eligible plants inquiring about converting to NPIS.

#### BIOTECH REVIEW IN APHIS

*Question.* One issue that has been raised by this Subcommittee is the backlog of applications for biotech products. I am pleased at the Department's efforts to clear out the backlog and hope those applications can be cleared by the end of this fiscal year. Moving forward, how can we further improve and shorten the process to put us on an even playing field with competing countries and give companies regulatory certainty?

*Answer.* Since 2012, USDA identified and implemented innovative ways to improve the biotechnology petition review process. The goal of these efforts was to significantly decrease the length and variability of the process without compromising the quality of the analysis that supports our decisions. Results of the 2012 process improvement are substantial. For example, published petitions are currently taking, on average, 1.8 years, a time savings of approximately 1.2 years over the petitions that did not require an environmental impact statement and were published between 2010 and 2012. USDA ensures that its environmental analysis and plant pest risk analysis documents are thorough, accurate, and can withstand legal challenges. The process improvement analysis revealed a minimum estimated timeframe of 13–15 months required to conduct quality analysis and solicit public input to support

regulatory decisions and protect plant health. These targeted timeframes are comparable to the average time it takes for product deregulation in other countries around the world. USDA appreciates the efforts of Congress to provide the necessary resources to USDA's biotechnology program and its continuing efforts to oversee certain genetically engineered organisms that might pose a risk to plant health. The President's fiscal year 2016 budget proposal for biotechnology regulatory services will provide sufficient funding to meet the new process timelines.

#### RICE ENTERING CHINA

*Question.* The U.S. Animal and Plant Health Inspection Service (APHIS) has been working with the China Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) since early 2007 to develop the mechanism to allow US rice entry into the China market. The current negotiation centers on a phytosanitary protocol, which sets out the technical requirements for US rice entering China. It is our understanding that the last official communication on the draft protocol was spring of 2014 when APHIS provided a response to the Chinese latest offer. In the last three scheduled bilateral meetings between APHIS and AQSIQ, one was canceled by the Chinese without explanation and at the other two AQSIQ did not have present the appropriate parties to negotiate on rice. It appears as though the Chinese are dragging their feet and not negotiating in good faith on this issue.

Since APHIS cannot compel their Chinese counterparts to negotiate, what more is USDA prepared to do to move this issue to an amicable solution?

*Answer.* To date, China has not authorized imports of U.S.-origin milled rice, but we understand that China is an important potential market for United States rice exports. The issue has been addressed in bilateral meetings with both Beijing-based and Washington-based USDA personnel. Since the spring of 2014, there were several letter exchanges with China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). The latest letter from AQSIQ, reworked the original language in the proposed draft protocol, but did not address a key USDA objection on the requirement of pest-free production sites. USDA shared the information with United States industry and rice producers, and together we are working to develop a solid technical response. From the USDA perspective, we expect to participate in on-going negotiations with China in fiscal year 2016, about the AQSIQ rice storage site requirement to more accurately reflect current pest management measures in U.S. rice storage facilities.

---

#### QUESTION SUBMITTED BY SENATOR SUSAN M. COLLINS

##### POTATO WART

*Question.* Potato wart is a serious, internationally-quarantined disease of cultivated potato that is not known to be present in the United States. The fungus is present, however, in Prince Edward Island, Canada, a region that is approved to export potatoes to the United States, which is the subject of significant concern to potato growers in Maine.

With few effective measures to control the fungus, potato wart is readily transmitted to new areas in a variety of ways: by tubers grown in infected soil, by tools used in potato cultivation, by footwear, and by manure from animals that have fed on infested tubers. Even more problematic is that infested tubers do not always show outward signs of infection.

Effectively controlling potato wart is possible primarily by appropriate production and handling practices, as well as statutory measures.

I commend APHIS for acting quickly in issuing the current Federal Order with respect to potato wart. I am concerned, however, that it does not address soil, machinery, or potato movement from PEI to other areas in Canada. Unrestricted movement of these materials from PEI to other potato producing areas of Canada is troubling because it risks spreading disease beyond PEI, including into the United States. This risk comes from the movement of these materials.

Will you evaluate the current Federal Order to help ensure that it is effectively protecting the potato industry in the United States, including in Maine, from being contaminated by this fungus that has the potential to devastate our industry?

*Answer.* I recognize your concern about preventing the introduction of potato wart into the United States. USDA has worked closely with the U.S. potato industry, States, and our Canadian counterparts to put in place a scientifically-based policy that allows for the safe importation of potatoes from Canada. As a result of the recent new detections of potato wart on Prince Edward Island (PEI), the Animal and Plant Health Inspection Service (APHIS) issued a Federal Order strengthening our

import requirements for potatoes from that province. The revised requirements apply to potatoes for consumption, processing, and seed from fields outside the regulated area, and were agreed upon by the U.S. Potato industry. The Canadian Food Inspection Agency (CFIA) quarantines infested fields and fields associated with them and conducts measures (monitoring, surveillance, and movement restrictions for potatoes as well as soil) to prevent further spread of Potato Wart within and from PEI to other parts of Canada or in exports. The measures also include prohibition of exports of potatoes from regulated fields to the United States and require that machinery used on regulated fields be cleaned and disinfected according to CFIA regulations before it can be moved. Under the Federal Order, potatoes from non-regulated areas of PEI must meet requirements to mitigate the risk of potato wart, such as washing to remove soil, sprouting inhibition, and phytosanitary inspection. Seed potatoes must originate from a field that has been tested and found free of the fungus that causes potato wart within 1 year of harvest. The Federal Order was put in place as an interim measure in response to concerns about possible risks from areas of PEI not regulated by Canada. APHIS and CFIA have committed to further technical discussions to review the current regulatory approach and if necessary, to make changes to the regulatory framework or other approaches to prevent the introduction of the disease into the United States while minimizing negative impacts on trade. Importation of PEI potatoes for non-propagative uses and for seed plays a significant role within the U.S. economy. USDA has worked to preserve this important import trade while protecting the U.S. industry from the risk of potato wart.

---

#### QUESTIONS SUBMITTED BY SENATOR STEVE DAINES

##### CONSOLIDATION OF FOOD SAFETY AGENCIES

*Question.* Earlier this month before this subcommittee, I voiced concerns I've heard regarding the President's proposal to consolidate food safety agencies into a new agency entirely within HHS. In that hearing, FDA Commissioner Hamburg stated that FDA and USDA have "very different approaches" and "different areas of expertise" as it relates to food safety.

Would you agree with Dr. Hamburg's assessment and the idea that USDA brings expertise and a unique perspective to the table regarding food safety?

*Answer.* While USDA does bring expertise and a unique perspective to food safety and while the U.S. food safety system is among the safest in the world, consolidating food safety functions is an essential step to reforming the Federal food safety system overall. A single Federal food safety agency would provide focused, centralized leadership, a primary voice on food safety standards and compliance with those standards, and clear lines of responsibility and accountability that will enhance both prevention of and responses to outbreaks of food-borne illnesses. It would rationalize the food safety regulatory regime and allow the Federal Government to better allocate resources and responsibilities.

*Question.* Are you concerned about the potential loss of expertise if USDA is removed from the food safety process?

*Answer.* The Budget highlights several opportunities for reorganizing and reforming government, including the new proposal to consolidate USDA's Food Safety and Inspection Service and the food safety components at FDA into a single new agency responsible for food safety inspection and enforcement, and foodborne illness outbreak prevention and response. The new agency would be charged with pursuing a modern, science-based food safety regulatory regime drawing on best practices of both agencies, with strong enforcement and recall mechanisms, expertise in risk assessment, and enforcement and research efforts across all food types based on scientifically supportable assessments of threats to public health.

*Question.* How would USDA ensure that agriculture's perspective and concerns are accounted for should such a consolidation occur?

*Answer.* While the Administration believes that this is an opportunity to drive efficiency and accountability, prevent duplication, and make government work better and smarter for the American people, USDA will still work to ensure that USDA and agriculture's perspectives and concerns are taken into account when consulting with the new agency.

##### ENVIRONMENTAL CONCERNS WITHIN THE DIETARY GUIDELINES

*Question.* In the fiscal year 15 Omnibus, there was a Congressional directive that expressed concern that the advisory committee was "showing an interest in incorporating environmental factors into their criteria" and directed the Secretary to

“only include nutrition and dietary information, not extraneous factors” in the final guidelines.

As you know, the Scientific Report of the 2015 Dietary Guidelines Advisory Committee was just released last month. It included, and I quote, “environmental approaches are needed to complement individual-based efforts to improve diet and reduce obesity and other diet-related diseases.”

Is the advisory committee report compliant with the Congressional directive?

*Answer.* As noted above, the Congressional directive is aimed at the Departments, not the Advisory Committee. Congress did not mandate that HHS and USDA use an Advisory Committee to review evidence, so it does not specifically define or limit what the Advisory Committee considers. It’s worth noting that the Committee’s report is advisory in nature—it is not a draft of the Dietary Guidelines for Americans. Additionally, the 2015 Advisory Committee used the terms “environment”/“environmental” in a variety of ways in its advisory report.

*Question.* In a hearing before the House Agriculture Appropriations Subcommittee, you indicated that USDA needs to “color inside the lines” with regards to the directions you’ve received from Congress. Can you confirm that the final report will follow Congressional intent and focus only on nutrient and dietary recommendations, and not factor in environmental factors and other extraneous material?

*Answer.* Working with our colleagues at the US Department of Health and Human Services, we will follow the statutory parameters for the Dietary Guidelines for Americans, focusing on providing food-based dietary recommendations that are grounded in the strongest body of scientific evidence.

*Question.* Do you believe that environmental issues are within the purview of developing these dietary guidelines?

*Answer.* While environmental issues are important overall and are a priority for USDA elsewhere as they intersect with the food supply, I do not believe they are within the confines of our Congressional mandate for development of the Dietary Guidelines. As the National Nutrition Monitoring and Related Research Act of 1990 (NNMRRRA) stipulates, the Dietary Guidelines for Americans, published by USDA and HHS “shall contain nutritional and dietary information and guidelines for the general public,” and we will focus on food-based, dietary recommendations based on the strongest evidence on diet and health.

#### U.S. SHEEP EXPERIMENT STATION

*Question.* The U.S. Sheep Experiment Station in Dubois, Idaho, has improved the knowledge and understanding of how the interaction between domestic and bighorn sheep may impact wild sheep herds, which has resulted in improved health for both domestic and wild sheep. Last year, USDA attempted to reprogram funds and would’ve shuttered the program if Congress didn’t intervene.

Can you commit to not attempting to reprogram funds from the USSES or make other efforts to close the station?

*Answer.* ARS’ ability to conduct innovative grazing research at the U.S. Sheep Experiment Station (USSES) continues to be negatively impacted by changes in domestic sheep access to grazing lands. This reduction in access is the result of changes in the areas permitted for grazing by domestic sheep to minimize contacts with expanding bighorn sheep populations and conflicts within the grizzly bear habitat in the Greater Yellowstone area. A variety of other factors, including a continued lack of resources, both human and financial, and inadequate infrastructure have contributed to the unsustainability of the ongoing research program at the USSES. USSES will remain open and operational during fiscal year 2015 to allow further input to be provided by stakeholders. However, given the ongoing, serious challenges to operating USSES, the fiscal year 2016 Budget for ARS does include a proposal to close the USSES and reprogram the associated funding to high priority research at other ARS locations in Idaho as the program is not sustainable.

The proposed closure of the USSES will not, however, negatively impact our research, knowledge, or understanding of sheep health, as sheep research will continue elsewhere.

---

#### QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY

##### HEALTHY FOODS FINANCING INITIATIVE (HFFI)

*Question.* Mr. Secretary, will you please discuss progress and successes to date of the Administration’s Healthy Foods Financing Initiative (HFFI)?

In the absence of funding so far for this program, USDA has developed background information and scoped out a path forward. USDA has discussed this program with other Federal agencies (Treasury and HHS) that deal with healthy foods to ensure coordination and to avoid/minimize duplication and with stakeholders. USDA has engaged with stakeholders and dialogue on best practices, models, ongoing policy efforts, areas where partners and agencies can collaborate, and other topics that would help inform the strategy for how the mission area can effectively deliver the HFFI program. Key areas discussed to date include:

- Process and selection of the National Fund Manager
- The role and duties of the National Fund Manager
- Process for soliciting and reviewing applications
- Contents of a regulation

What has USDA been able to do to support the HFFI under USDA's current authorities?

*Answer.* Without funding explicitly provided, USDA's ability to implement the Healthy Food Financing Initiative and to begin to finance retail food providers in areas with limited food access through a national fund manager has been severely restricted. The USDA and Rural Development have used existing programs and authorities to support efforts to increase access to healthy food. For example, in fiscal year 2014, USDA Rural Development through the Business and Industry Guaranteed Loan Program, Rural Business Enterprise Grant Program, Rural Business Opportunity Grant Program, Value Added Producer Grant Program, Rural Cooperative Development Grant Program, Small Socially Disadvantaged Producer Grant Program, and Rural Energy for America Grant Program was able to fund 231 projects totaling over \$77.4 million which assisted rural businesses in providing healthy food.

*Question.* This budget requests \$12.8 million for Rural Development's participation in the initiative. Please explain how these funds would be used and what you expect to accomplish.

*Answer.* The funds requested for the Healthy Food Financing Initiative would enable Rural Development to seed a fund that through a third-party fund-manager would provide loans, grants and technical assistance to low-income and moderate-income communities for investments that would increase access to healthy food. Rural development would write the rules and regulations for the program, but a third-party, the fund-manager would then run the program.

Ultimately, the awards made will support market planning and promotion efforts as well as infrastructure and operational improvements designed to stimulate consumer demand, enhance marketing, expand demand and retail outlets for farm products, and increase availability of locally and regionally produced foods.

Funding would be made available to the following entities with sound strategies for addressing the healthy food needs of communities: businesses, non-profits, public entities, and community development financial institutions.

The funds will be targeted to severely underserved low- and moderate-income communities. Most often low-income communities are less attractive, under the conventional financing, to retailers of healthy food. However, effective programs have shown that well-targeted financing and technical assistance can create viable business outcomes and access to healthier foods and create new markets for farmers, but also create jobs and support broader development efforts to revitalize distressed communities.

Organizations will use grants, below-market rate loans, loan guarantees and tax credits to attract private sector capital for an even greater investment in projects that increase access to fresh produce and other healthy foods. The goal is to support efforts to provide access to healthy foods in underserved areas, to create and preserve quality jobs, and to revitalize low-income communities.

USDA Rural Development will work in close coordination with USDA's Food and Nutrition Service and Agricultural Marketing Service in crafting and administering the program to ensure the goal of expanding healthy food access is achieved.

#### APHIS OVERALL BUDGET PRIORITIES

*Question.* Mr. Secretary, APHIS is charged with protecting the U.S. from invasive animal and plant pests and diseases. This budget reflects priority funding for: antimicrobial resistance activities in the Zoonotic Disease Management program; Agricultural Quarantine Inspections; "citrus greening" (huanglongbing); and expanded implementation of Lacey Act enforcement. These are laudatory priorities, but I have several questions.

In this era of severe resource limitations, please explain your review process through which these priorities rose to the top.

*Answer.* Our Blueprint for Stronger Service has saved American taxpayers a total of \$1.368 billion over the last several years while ensuring that the American people receive the best service possible. While developing the fiscal year 2016 Budget, USDA focused on areas that would have a broad, national or international impact and improve our nation's economy and agricultural health, assisting rural communities and ensuring access to safe nutritious food for all consumers. USDA is supporting a government-wide initiative to deal with antimicrobial resistance, which affects both animal and human health. The Animal and Plant Health Inspection Service (APHIS) will play an important role in this effort by monitoring for antimicrobial resistant bacteria among livestock. The other increases support APHIS' mission of protecting the health and value of U.S. agriculture and natural resources. These increases will allow APHIS to meet critical needs related to its mission, and they also fit into USDA's goals of supporting rural economies and ensuring access to safe and nutritious foods.

*Question.* Within the Specialty Crops Pests program, for citrus greening, you are requesting \$3 million in new funding plus \$4.5 million in redirected funding. However, total Specialty Crops Pests support would be reduced by \$10.8 million. Such a reduction would severely curtail control and eradication efforts on a variety of devastating pests including: European Grapevine Moths; Light Brown Apple Moths; Medflies; glassy-winged sharpshooters; and the spotted wing drosophila. According to your budget, in fiscal year 12 this program protected \$27 billion worth of specialty crop production in this country.

As you know, Oregon is a major producer of specialty crops. What assurances can you provide that this funding reduction will not impact our fruit, vegetable, nuts, horticulture and nursery crops production?

*Answer.* USDA is proposing decreases to three areas of the Specialty Crop Pests program: the Citrus Health Response Program, the glassy-winged sharpshooter program, and the light brown apple moth program. These proposed decreases are designed to allow for more equitable sharing of costs between the Federal government and those who benefit from these important programs. If cooperators are able to increase their contributions to the programs, they will continue to operate at their current levels. If contributions to the programs do not increase, APHIS would focus available resources on preventing the spread of the pests and diseases to new areas.

#### AVIAN INFLUENZA

*Question.* Recently new cases of highly pathogenic avian influenza have been detected in Michigan, Missouri, and Arkansas. This disease can be transmitted by wild birds and has impacted both commercial and backyard flocks. Selective trade restrictions have been imposed by numerous countries affecting U.S. poultry exports. However, this budget requests only a \$55,000 increase for the Avian Health program.

In the face of these newly detected cases of bird flu do you still believe this funding level is adequate to protect the U.S. poultry industry and maintain poultry exports?

*Answer.* We developed our fiscal year 2016 budget request before the bird flu outbreak escalated to the extent that it has today. We are monitoring this situation closely, and are keeping our trading partners fully informed. To address this issue, we are using appropriated and emergency funding carried over from previous years as well as funds appropriated in fiscal year 2015 to carry out response actions. These actions include indemnifying producers and conducting surveillance activities in areas near detections. If we find that we cannot adequately address the situation through these funding sources, we will pursue emergency funding sources.

*Question.* What access do you have to Commodity Credit Corporation funds to address emergencies of this sort?

*Answer.* I am authorized to quickly access and transfer funds from the Commodity Credit Corporation to any USDA agency in the event of an agricultural emergency. As part of the process, the Office of Management and Budget reviews the emergency funding request to ensure consistency with Administration priorities and apportions the funding accordingly.

#### IMPLEMENTATION OF NEW METHODS OF POULTRY SLAUGHTER INSPECTION

*Question.* Mr. Secretary, the Food Safety and Inspection Service is responsible for the safety and accurate labeling of domestic and imported meat, poultry and processed egg products. This is generally accomplished through in-plant inspections carried out by a cadre of FSIS inspectors. Your budget proposes to cut overall agency funding by \$4.9 million, chiefly relying on \$10 million in savings to be achieved by implementation of new methods of poultry slaughter inspection.

Mr. Secretary, you have been working toward implementing these new methods of inspection for several years. Have you made sufficient progress to achieve these savings in fiscal year 16?

*Answer.* With the publication of the final rule in August 2014, we plan on being able begin implementation and anticipate the first plants converting by the end of fiscal year 2015. Our fiscal year 2016 estimate is based on the timeline in the final rule which estimated implementation going from fiscal year 2015 through fiscal year 2019.

*Question.* We continue to hear concerns that these new inspection methods will sacrifice food safety for expediency. What assurances can you provide that the safety of our food supply will not be compromised by this new process?

*Answer.* As a result of the new rule, the bacterial testing requirements for all plants, including those who elect to participate in the new system, as well as those who retain their existing system, will be required to perform both pre-chill and post-chill bacterial testing, effectively doubling the testing requirements for pathogens such as Salmonella and Campylobacter. The FSIS Risk Assessment based on the best science available, presents estimates that industry-wide adoption of NPIS would reduce the number of human illness, attributed to young chicken and turkey products by an average of about 3,980 Salmonella illnesses and about 840 Campylobacter illnesses annually. Our data has shown that the HIMP model plants, on which the New Poultry Inspection System is based, have food safety records that are as good as, or better than, that of the traditional slaughter plants.

*Question.* We also hear concerns that the accelerated carcass line speeds will jeopardize worker safety. I understand that those plants participating in the pilot program will continue to be allowed to move poultry carcasses at 175 birds per minute. That is an astounding speed—equal to three carcasses a second. What type of inspection can conceivably take place in 1/3 of a second? What studies have you undertaken and what information can you provide that these line speeds will not threaten worker safety?

*Answer.* In response to public comment, the maximum line speeds for plants that adopt the NPIS are capped at 140 birds per minute, consistent with the maximum speed under existing inspection programs. Plants that participated in the pilot program will be allowed to maintain line speeds of 175 birds per minute. USDA received numerous comments on the proposed rule related to work safety and has partnered with Federal agencies responsible for worker safety to address those concerns.

#### MERGING FOOD SAFETY RESPONSIBILITIES

*Question.* Mr. Secretary, there is a very brief write-up in the budget appendix indicating the President is asking for reorganization authority to merge all food safety responsibilities into one agency, to be housed in the Department of Health and Human Services (DHHS).

Will you please describe, in more detail than provided in the budget, what this proposal entails?

*Answer.* The Budget highlights several opportunities for reorganizing and reforming government, including the new proposal to consolidate USDA's Food Safety and Inspection Service and the food safety components at FDA into a single new agency responsible for food safety inspection and enforcement, and foodborne illness outbreak prevention and response. The Administration believes that this is an opportunity to drive efficiency and accountability, prevent duplication, and make government work better and smarter for the American people.

*Question.* Is a legislative proposal forthcoming on this reorganization?

*Answer.* The Budget demonstrated examples of what the President would do if Congress reenacted broad reorganization authority. The Administration believes that this is an opportunity to drive efficiency and accountability, prevent duplication, and make government work better and smarter for the American people.

*Question.* Can you provide assurances that the food safety expertise developed in the Food Safety and Inspection Service will not be eroded through this reorganization?

*Answer.* USDA and FDA have strong collaborative ties that have improved Federal coordination of the nation's food safety system. The new agency would be charged with pursuing a modern, science-based food safety regulatory regime drawing on best practices of both agencies, with strong enforcement and recall mechanisms, expertise in risk assessment, and enforcement and research efforts across all food types based on scientifically supportable assessments of threats to public health.

## RENTAL ASSISTANCE

*Question.* Mr. Secretary, the Department's Rental Assistance program subsidizes certain tenants of affordable rural housing to pay no more than 30 percent of their adjusted household incomes on rent and utilities. Recipients of Rental Assistance are, generally, the elderly, disabled, or female-headed households, with average annual household incomes around \$10,000. This budget seeks an \$83.4 million increase in rental assistance.

In addition, the budget requests four program "reforms" that would appear to severely disadvantage very low income program participants. The Committee rejected three of these reforms in fiscal year 15 while accepting the fourth. However, now program advocates are voicing strong opposition to all four.

Please explain the four Rental Assistance program reforms and how their implementation would not jeopardize the security of very low income tenants.

*Answer.* The legislative changes the Administration has requested help ensure that the Rental Assistance (RA) program will continue to provide a safety net for the neediest rural residents and ensure the program's long-term sustainability. Prudent program management demands that Rural Development (RD) ask for adequate funding and seek authority to control program costs in times of budgetary constraints. On balance, the legislative proposals further concentrate the benefit of RA for the most disadvantaged rural households and extend the available funding to as many properties, and tenants, as possible.

#### *No automatic renewals*

Current statutory language requires that funding on an RA Agreement be automatically replenished when funds are exhausted. RD's estimating methodology on funding amounts ensures that all RA agreements have enough funding for the full 12-month period. However, the Department has experienced the need for a second obligation in the same 12-month period in 3—5 percent of the renewals in a fiscal year. These automatic renewals will need to be funded for 12 months again.

Having to fund these second renewals means some properties receive a disproportionate share of RA funds, to the detriment of other properties, during a fiscal year. Having this authority will allow the Department to more efficiently utilize RA resources; these actions will also eliminate same uncertainty of future program costs and provide budget greater predictability for the RA Program.

#### *Selective renewals*

Selective renewals and partial year agreements are two proposals designed to stretch available RA funding during periods of short-term continuing resolutions or sequesters. During such uncertain funding periods, every RA Agreement that requires full 12-months' funding cannot be accommodated. RD seeks the selective renewals authority to eliminate the current practice of renewing agreements on a first-come-first-serve basis, without regard to need. Selected renewals will provide to the Department the ability to prioritize or determine renewals for properties where the need may surpass that of other properties.

#### *Partial year agreements*

Current appropriation language and statutory authority requires RD to obligate the entire 12-month estimated amount of RA funding at the time the agreement is renewed. In times when the budget is uncertain, such as during a short-term Continuing Resolution, providing RD with the ability to obligate less than a full-year of funds will provide RD with an important management tool that will help ensure RA is available for those who need it most. The result will be that the agency is better able to continue to meet its mission of providing affordable housing to residents even in times of funding uncertainty.

#### *Minimum rent*

RD's proposal is to institute a minimum rent of up to \$50 per month, but plans to start with a minimum rent of \$25 per month. This authority is similar to rental assistance programs at Department of Housing and Urban Development (HUD). RD intends to provide hardship exemptions for applicants and tenants who cannot pay the minimum, and eviction of tenants is prohibited if they cannot pay the minimum rent. The Department believes this change will encourage a sense of ownership within the rental community by tenants, as well as contribute to the long-term availability of RA. The hardship exemption will ensure that the minimum rent requirement does not jeopardize the security of very low income tenants.

*Question.* The \$50 per month minimum rent reform appears focused on the very lowest income program participants. The budget states that waivers would be granted in cases of extreme hardship. The budget also contends this reform will save \$5

million per year. Please explain the situation in which \$5 million could be raised without imposing substantial hardship on tenants.

*Answer.* The 2016 Budget requests the authority to require a minimum rent payment of \$50 per month regardless of tenant income level. The proposal includes hardship exemptions for tenants that can demonstrate they are unable to pay the minimum. These hardships may include the loss of family income due to the termination of employment, termination of benefits from other programs, or the death of an income earner. The proposal also prohibits the eviction of tenants if they are financially unable to pay the minimum rent.

There are currently about 42,000 households that pay between \$0 and \$50 per month as their tenant contribution toward the rent payment. The actual number that would see their tenant contribution increase to \$50 per month would depend on the number of exemptions approved.

Ensuring the long term viability of the RA program is in the best interest of the tenants, who have come to rely on the program to help support their ability to live in affordable housing and allow us to stretch this much needed resource. The hardship exemption will ensure that the minimum rent requirement does not jeopardize the security of very low-income tenants.

*Question.* Is the agency working to develop other cost containment strategies that would not endanger the security of very low income rural residents?

*Answer.* The well-being of low and very-low income rural Americans is a top priority for this Administration and the Department of Agriculture. The cost containment strategies included in the President's 2016 budget request are intended to provide USDA with the tools for managing a program that provides essential support to rural Residents during a time of reduced budgets. The legislative proposals presented as cost containment strategies are a response to both budget reductions due to sequestration and legislatively-mandated changes—such as reducing the duration of RA agreements—that have forced USDA to manage the portfolio and growing need amidst an overall reduction in funds.

#### MULTI-FAMILY HOUSING PRESERVATION PILOT

*Question.* Mr. Secretary, over 16,000 affordable multi-family housing projects in rural America have been financed using USDA loans. These projects include over 475,000 housing units for low and very low income rural households. However, the average age of these projects exceeds 25 years.

With projects this old, what is the Department doing to maintain their physical condition and to mitigate issues of deferred maintenance?

*Answer.* USDA has long recognized the need to revitalize its existing Section 515 housing. The primary means of revitalization has been through the Multi-Family Preservation and Revitalization (MPR) program, which provides flexible financing tools that can be tailored to provide the best financing solution to each property's needs and ability to repay. To stretch the Department's dollars further, MPR revitalization is typically done through a public/private partnership that includes Low Income Housing Tax Credits and third party financing, along with MPR funds. The Department also works with Section 515 property owners to transfer aging properties to new owners ready and able to invest in the modernization of the property. USDA works to mitigate the risk of deferred maintenance by closely monitoring each property through onsite physical inspections and review of property financial conditions. This oversight ensures that properties are in safe and decent condition, and financial resources are set aside to address maintenance needs as they arise.

*Question.* Some years ago the Committee created a pilot program to address property rehabilitation needs and to protect tenants if projects prepay and leave the program. This budget indicates the Department will submit legislation to make that pilot a permanent program. What is the status of that proposed legislation?

*Answer.* The fiscal year 2016 budget request included the proposal to make permanent the Multi-Family Preservation and Revitalization (MPR) program. The 2016 budget follows similar requests to make the MPR program permanent in the fiscal years 2014 and 2015 budget. USDA believes the MPR program fills a critical need for flexible financing that can revitalize our rental housing without the need for significant increases in tenant rents to pay for it. The Department has delivered the legislative proposal to OMB for their consideration and transmission.

*Question.* What changes will the proposed legislation include compared to the existing pilot?

*Answer.* The proposal to make the MPR program permanent will provide the same financing tools Rural Development has been using in the pilot program. These tools include providing zero percent loans, soft second loans, grants for health and safety

repairs, and modification of existing loans. These tools have been very successful in meeting the needs of properties that have participated in the MPR program.

*Question.* Have you worked with housing advocates, owners, and other interested parties in the drafting of this proposal?

*Answer.* USDA has met frequently with housing advocates, owners, and other interested parties over the years in relation to the MPR and other Multi-family housing programs. I believe the proposal that has been drafted meets the needs of our Multi-family stakeholders.

*Question.* One concern we frequently hear is that the Department is unable to expedite the transfer of a property from the current owner to a non-profit purchaser. These transactions typically take 18 months or more, which places incredible burdens on the buyers in terms of holding together financial packages. What is the Department doing to streamline and accelerate this process?

*Answer.* RD has consulted with its customers and they have identified the process for transferring properties as one of the most in need of streamlining. RD has been working with stakeholders in a Lean Six Sigma improvement process to identify barriers to making the transfer process more efficient. Stakeholders have also recommended process improvements that will reduce processing times, provide transparency into the transfer process, create a consistent set of transfer requirements, and create predictability. Currently, Rural Development is working to implement several of these process improvements. These include: 1) providing buyers, sellers and other parties with a preliminary assessment tool they can use to test the terms of their transfer prior to submission to Rural Development; 2) developing a simpler, easier to use underwriting tool that incorporates more industry standards in transfer underwriting; and, 3) revising Multi-family handbooks to formalize these changes in underwriting policy.

*Question.* Tenants currently residing in two Section 515 financed properties located in Merrill and Myrtle Creek, Oregon are in danger losing their Rental Assistance subsidized housing this summer due to the underlying mortgages reaching maturation. Will you commit to using your authority to extend these mortgages for a short period of time to give the willing and qualified sellers and buyer's sufficient time to preserve these two properties?

*Answer.* Rural Development is preparing to issue guidance to Multi-family Housing staff, outlining steps to take on maturing mortgages, including the ability to offer short-term or long-term mortgage re-amortization to keep properties in the MFH portfolio and continue to provide affordable housing to residents. Owners will also be encouraged to participate in the MPR program, which would enable them to take advantage of a long-term debt deferral. If owners decline both of those offers, we strongly suggest they request prepayment, which would enable the property's tenants to receive offers of an RD Voucher.

*Question.* Is there anything this Subcommittee can do to assist you with these issues?

*Answer.* The Department currently offers portable housing vouchers to tenants of affordable housing projects that were financed with USDA loans, and whose owners pre-pay and leave the program. The Administration has proposed to expand eligibility to tenants of projects whose mortgages have matured and been paid off in the 2016 budget.

We would appreciate the support of the Subcommittee for this proposal. In addition, constituent stakeholders interested in purchasing a maturing project, should contact the RD State Office and submit a transfer application. Once the State Office receives a complete application, it can prioritize the processing. If the potential purchaser is not familiar with RD's transfer process, our State Office stands ready to help.

#### HOUSING VOUCHERS

*Question.* Mr. Secretary, the Department currently offers portable housing vouchers to tenants of affordable housing projects that were financed with USDA loans, and whose owners pre-pay and leave the program. The Administration proposes to expand eligibility to tenants of projects whose mortgages have matured and been paid off.

This budget requests \$15 million in fiscal year 16. Is that sufficient both to renew all expiring vouchers and to fund new vouchers stemming from pre-payments and maturing mortgages?

*Answer.* RHS believes that the \$15 million level will be sufficient to renew all expiring vouchers and allow for funding prioritization for new vouchers as demand warrants, including the proposed expansion of the Voucher program to tenants in properties with maturing mortgages. With the Department's initiative to retain as

many maturing mortgage properties as possible, we believe the proposed funding level will accommodate the need for new vouchers for these tenants.

*Question.* Do you expect the demand for vouchers to grow significantly due to including tenants in maturing mortgage properties?

*Answer.* There will be a small increase in demand, which we have accounted for in our estimates. In 2015, we have focused our efforts on outreach to owners of properties with maturing mortgages, working with them to find ways to keep them in the program if they are willing. So we believe going forward we will be more successful retaining our Section 515 properties in the program.

RD's initial efforts have succeeded in 2014, where 10 of the 14 properties expected to leave have remained in RD's portfolio. As the initiative gains momentum and visibility, we believe more owners will take advantage of the incentives we offer.

#### SELF-HELP HOUSING PROGRAM

*Question.* The Department's self-help housing program provides grants to non-profit organizations that coordinate small groups of families aspiring to achieve homeownership through the self-help method. These families jointly work on their houses, contributing sweat equity that ultimately lowers their purchase prices.

Mr. Secretary, this is one of the most popular programs in this bill. Please explain why this budget slashes the program by 64 percent?

*Answer.* The Mutual and Self-Help Housing Program has played an important role in providing opportunities for affordable housing for low and very low-income families in rural America for 50 years. The requested 2016 funding level for Mutual and Self-Help housing grants would, paired with balances from prior years, address the reduction proposed in this program. However, because of budget constraints, funding for this program in 2016 it would not support the anticipated demand associated with the increased program level in Section 502 Single Family Direct.

*Question.* It is our understanding that these families are the stars of your housing programs, in terms of making timely payments and achieving successful homeownership. Do you know of any other Federal program more effective than this in accomplishing these objectives?

*Answer.* The Mutual and Self-Help Housing program is unique among Federal housing programs, serving the lowest income families who would otherwise be unable to attain homeownership. The Mutual and Self-Help Housing Program has played an important role in providing opportunities for affordable housing for low and very low-income families in rural America for 50 years. There is no other Federal program.

#### BROADBAND PROGRAM

*Question.* Mr. Secretary, USDA has had the responsibility for some years of expanding access to high speed broadband services across rural America.

Please discuss your view of the success the Department has achieved to date in this effort.

*Answer.* The most significant success the USDA has achieved was the delivery of the Broadband Initiatives Program (BIP), a Recovery Act program. There are 255 active infrastructure projects and approximately \$2.7 billion has been advanced for construction. As a result of Recovery Act funding, more than 213,000 households, 15,000 businesses, 570 public safety facilities, 460 healthcare providers and more than 700 schools and libraries are receiving new or improved broadband service.

The Department also runs two other successful programs to deploy broadband. The Rural Telecomm Program and the Community Connect Program. In our infrastructure program this year, we have approved \$190 million in financing that will enhance broadband service to over 65,000 customers. Community Connect provided \$20.3 million to fund broadband in unserved communities in fiscal year 2014. The rules for the 2014 Farm Bill Broadband Program are in progress and the program will start once the new regulation is published later this year.

*Question.* The fiscal year 14 Farm Bill required changes to the USDA loan program. Please let us know the status of those regulation changes, and when you expect that revised program to be in operation.

*Answer.* USDA, specifically the Rural Utilities Service (RUS), continue to work closely with OMB to finalize the regulations for the broadband loan program. USDA anticipates this process to be finalized in the summer of 2015 and will begin to immediately start accepting applications once the NOSA is posted on the Federal Register.

*Question.* What can this Subcommittee do to help you promote high speed broadband access in rural America?

*Answer.* The Subcommittee could provide funding for the Farm Bill broadband program in line with the President's fiscal year 16 budget request to help fund broadband in unserved and underserved rural areas.

#### RURAL CHILD POVERTY PILOT INITIATIVE

*Question.* Mr. Secretary, this budget seeks \$20 million for a pilot initiative to address severe rural youth poverty.

Please describe how this initiative will work.

*Answer.* The Administration's fiscal year 2016 Budget proposes \$20 million for a new program to support innovative strategies that combat rural child poverty by focusing on both children and the parents with a bundled services approach. This approach incorporates three elements:

- Pilot program to create better coordination of current Federal programs designed to help poor kids and families, with a focus on helping the parents obtain employment and increase their income;
- Human resources to perform critical coordination and outreach work; and
- Rigorous evaluation to determine the efficacy of the approach for broader implementation.

Eligible uses would include educational or job training instruction for parents coupled with child-focused programming and support relating to health and early learning. The pilot will educate families on resources available, build local capacity for assisting families in rural areas through AmeriCorps or VISTA programs. Additionally, the pilot will support development and maintenance of an integrated client and services tracking system to instantly determine client eligibility across Federal programs and better meet the array of client needs. The resources in this pilot would complement other dollars in the budget that assist communities and nonprofit organizations to finance the physical infrastructure needed to deliver services, particularly through the Community Facilities grants and the Distance learning programs. Applicants could include local governments (but not States), educational institutions (including community colleges as well as historically black, tribal, or Hispanic institutions), and community action agencies. Pilot program funds would be provided exclusively to projects that are located in areas of high poverty and that have embraced a bundled service, "two-generation" approach that focus on both the children and parents of low-income rural families. The maximum amount of the grant would be \$500,000. The grants would encourage or require collaboration and partnerships of key entities at the local level. For example, the applicant may be a community action agency that traditionally delivers temporary assistance to needy families (TANF) resources and Early Head Start, and a Women, Infants, and Children enrollment center and in its application includes the local community college to deliver workforce development programs.

*Question.* What empirical metrics have you identified to evaluate the success of the pilot?

*Answer.* An outside evaluator group will be contracted to:

- develop (in conjunction with Rural Development) appropriate measures to allow an evaluation of the pilot program, and
- implement experimental and quasi-experimental impact evaluations to evaluate the program's effectiveness.

The evaluation work will identify best practices and provide information and recommendations on potential expansion of Federal investment around the "bundled" service delivery approach.

*Question.* Will you have enough time to demonstrate that these activities can be successful?

*Answer.* If the funding requested is provided in fiscal year 2016, USDA plans to announce, select and fund "bundled" service projects in 2016. Projects will provide services in 2016 and 2017. Pilot project evaluation will take place in 2018.

#### COMMUNITY FACILITIES GRANTS

*Question.* Community facilities loans and grants can be used for almost any essential community facility, including; schools; hospitals; clinics; libraries; public buildings; child and elderly day care facilities; health and safety vehicles and equipment; etc. This budget requests a 285 percent increase in the regular community facilities grant program.

What is the purpose of this huge increase in these grants this year?

*Answer.* Additional Community Facilities (CF) grant funds will enable RD to support investments in critical community infrastructure in high need, high poverty areas such as Promise Zones, the Coal Community Revitalization initiative and Strike Force among others, where there is limited ability to carry a loan. The in-

crease in the grant program is comparable to the increase the CF direct loan program has experienced in the recent years. These additional CF grant investments will be targeted to those communities that need help the most.

The USDA Community Facilities program has proven a particularly effective tool for fostering partnerships and leveraging other sources of funding. Additional grant dollars will only increase RD's ability to do this while ensuring that these investments are made in places where they are needed most.

*Question.* Do you plan to pair these grants with the large (\$2.2 billion) loan program to achieve a more effective combination loan/grants Community Facilities program?

*Answer.* CF grant funds will be targeted to those communities that need the help the most, i.e. Strike Force, Promise Zones, and other high poverty areas. Applicants with the financial capacity to repay a direct loan at reasonable rates and terms may leverage loans funds with competitive grant funds to help reduce total project cost and strengthen the financial viability and project sustainability. Some of these grant funds may be paired with loan funds, but it is expected that communities in high poverty areas will be unable to afford much debt, so most of these additional grant funds may not be paired with loan funds.

#### LOCAL AND REGIONAL PROCUREMENT

*Question.* According to a 2013 Cornell study of three countries, food aid recipients were unconditionally more satisfied with LRP compared to US shipped commodities. This sentiment was most pronounced among the poorest "less-well-off" recipients.

What steps are being taken to ensure that commodity foods shipped are compatible with local tastes and dietary needs?

*Answer.* The McGovern—Dole International Food for Education and Child Nutrition Program is USDA's primary international feeding program. The school meals and take home rations provided under McGovern-Dole address dietary deficiencies. McGovern-Dole projects are conducted by non-profit charitable organizations, cooperatives, the United Nations World Food Program and other international organizations. These implementing partners that USDA works with on the ground are instrumental in determining the proper foods to ship. All proposals submitted must provide a justification for the commodities being recommended as well as a full explanation of how the commodities meet the dietary needs of the beneficiaries.

Additionally, USDA's implementing partners and their sub-recipients often go to the recipient country to develop and test recipes that are suitable to the local tastes and dietary needs. USDA's implementing partners also work with local communities and farmer groups who provide local commodities to add to the school meals, thereby helping to tailor the meals to local preferences. Many schools have gardens, with the produce used to complement the U.S. commodities in the school meals.

*Question.* If U.S. shipped commodities are not found to be compatible with local tastes and dietary needs, what steps are taken to address this problem and ensure beneficiaries are actually utilizing U.S. commodities?

*Answer.* USDA's implementing partners and their sub-recipients often go to the recipient country to develop and test recipes that are suitable to the local tastes and dietary needs. USDA's implementing partners also work with local communities and farmer groups who provide local commodities to add to the school meals, thereby helping to tailor the meals to local preferences. Many schools have gardens, with the produce used to complement the U.S. commodities in the school meals.

*Question.* When coupled with existing programs that strengthen local community systems and infrastructure, LRP can be adopted by knowledgeable beneficiaries with consideration given to impacting local markets. Given that most food assistance programs include a local capacity building component (McGovern/Dole FFE, Title II non-emergency programming) has there been any consideration for use of LRP to help transition to locally available products in these programs?

*Answer.* USDA's food aid programs, particularly McGovern-Dole, are intended to ultimately be transitioned to host country governments. As such, there is every hope and intention that the LRP will help in assisting this transition by using locally available products as a source for food aid programs that will ultimately spur economic development in countries where these programs are implemented.

*Question.* If appropriated, how would the \$20 million for LRP be utilized?

*Answer.* The \$20 million for LRP requested in the President's budget is expected to support three to four development programs, similar to those in Bangladesh, Nicaragua and Mozambique supported by the LRP pilot program, and completed in 2012. The program will serve as a complementary tool to existing food aid programs, especially the McGovern-Dole international School Feeding Program. Under the LRP program, grants will be provided to eligible organizations including private vol-

untary organizations, cooperatives, and the World Food Program to implement projects involving local farmers, farmer organizations, parent groups and local governments.

*Question.* Besides working with McGovern-Dole programs, do you see an opportunity to pair the new LRP program with Title II non-emergency programs?

*Answer.* USDA and USAID communicate regularly on programming decisions to avoid duplication and understand areas for potential collaboration. For USDA's LRP funding, the two agencies will continue to explore opportunities to leverage our respective programs. For example, one possible area of collaboration would be if McGovern-Dole school feeding programs bought a portion of the commodities for school meals from associations supported by Title II non-emergency or Bureau of Food Security programs. Such opportunities would need to be evaluated on a country by country basis.

#### FOOD FOR PROGRESS

*Question.* Please provide the subcommittee with the average time it takes to put out a solicitation for a Food for Progress grant, review bids and award a grant to an implementing partner.

*Answer.* Grants under the Food for Progress program fund non-emergency, agricultural capacity building projects. Food for Progress projects, which are usually multi-year, have trained farmers in animal and plant health, improved farming methods, developed road and utility systems, established producer cooperatives, provided microcredit, and developed agricultural value chains. Program participants have included private voluntary organizations, foreign governments, universities, and intergovernmental organizations.

The average duration between publishing the Food for Progress (FFPr) grant solicitation to signing the agreement is approximately 190 days, including 90 days for interested organizations to submit proposals, and 100 days for USDA to review proposals and negotiate agreements.

*Question.* How does the length of time between solicitation and award for Food for Progress differ from Food for Peace?

*Answer.* USAID's average award time for non-emergency programs under Food for Peace is 228 days, while the average Food for Progress (FFPr) award time is 190 days.

*Question.* If there are delays of over 6 months between bids and awards, what are the major constraints that contribute to these delays?

*Answer.* The typical time between proposal receipt and award is 100 days. In fiscal year 2014, FAS negotiated the proposals within that timeframe. Complexities of projects and negotiations with implementing partners can impact the time to complete the agreement.

*Question.* Does Food for Progress have a policy that grants must be turned around in 120 days, similar to Food for Peace?

*Answer.* FAS is committed to ensuring that grants are turned around as quickly as possible, but does not have a policy that grants must be turned around in 120 days. Since these are development, not emergency, programs, and since the requests for Food for Progress greatly exceeds the limited resources, FAS has put in place an extensive review process to ensure that the awards are made to the best proposals that reach the greatest number of beneficiaries and have the highest degree of success.

*Question.* How many staff work on Food for Progress programs?

*Answer.* There are nine full-time equivalent employees working on Food for Progress programs. They are responsible for all aspects of Food for Progress projects, including planning, programming, monitoring, and grants management activities.

*Question.* Is there a staff shortage at Food for Progress that causes delays in processing of grants?

*Answer.* In late 2014, USDA initiated a human capital assessment of the Food Assistance Division that aimed to provide an independent assessment of workforce requirements for Food for Progress programs. The Foreign Agricultural Service is implementing the results of this independent assessment to ensure efficient and effective food aid programming.

*Question.* How does the number of staff at Food for Progress compare to other grant making offices in USDA? Or USAID?

*Answer.* There are nine full-time equivalent employees dedicated to planning and implementing the Food for Progress program. There are nine full-time equivalent employees who program the McGovern-Dole Food for Education and Child Nutrition

program. And 64 full-time equivalent employees working in USAID's Office of Food for Peace.

---

QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

USDA ASSISTANCE TO CALIFORNIA

*Question.* California is going into another year of drought. Ground water, snow pack, and reservoir levels are dangerously low. Communities like East Porterville are running out of drinking water, and both farmers and farm workers are suffering.

Are the funds requested in your fiscal year 2016 Budget sufficient to address California's worsening drought disaster?

*Answer.* The challenges facing drought-stricken areas are so severe that we will undoubtedly need to leverage Federal dollars and find innovative partners to help us provide as much relief as possible. Across USDA, we are actively working to address the needs of communities facing this historic drought. The Department is committed to assisting rural communities and we also know our partners are being innovative about what resources they can bring to the table.

Specific to the fiscal year 2016 request, the President's budget requested \$10 million in additional appropriated funding for Emergency Community Water Assistance Grants. While this increase may seem small given the magnitude of the problem, it is being coupled with application process improvements and the granting of priority to drought impacted communities. Collectively, these efforts should go a long way in providing safe, reliable drinking water in drought-stricken communities.

In addition to the increase within Rural Development, the fiscal year 2016 President's Budget includes a continuation of many other USDA programs that will assist producers in drought-stricken areas. For example, the permanent livestock disaster programs provided by the 2014 Farm Bill will be continued. Targeted conservation assistance for drought-stricken areas is another example of a successful program the Department plans to continue.

*Question.* What additional steps can your Department take to address this disaster across California?

*Answer.* Last year, President Obama and I travelled to Fresno, California to outline a drought relief action plan aimed at mitigating the impacts of this natural disaster for farmers, ranchers and residents alike. I'm proud to say that USDA met or exceeded the commitments we made over a year ago to these communities and I'm proud of the progress we've made. Unfortunately, the relentlessness of the drought has made the challenge confronting the Western U.S. increasingly serious. We continue to collaboratively deploy the resources made available to us and believe our budget request will position us to do even more in the year ahead. That said, the challenges facing these drought-stricken areas are so severe that we will undoubtedly need to leverage these Federal dollars and find innovative partners to help us provide as much relief as possible. Across USDA, we are actively working to address the needs of communities facing this historic drought.

PATHOGEN STANDARDS

*Question.* I am pleased your Department proposed new pathogen standards for poultry products in January. I believe these standards will improve food safety.

Can you tell me what date these will be finalized and implemented?

*Answer.* On January 26, 2015 FSIS issued a notice and request for comments on performance standards for chicken parts and the new standards for comminuted chicken and turkey. While I cannot provide a precise date when the new standards will be finalized and implemented, let me assure you that these standards are an Agency priority, and we will move as quickly as possible.

*Question.* Secretary Vilsack, I remain deeply concerned about the persistent rates of foodborne illness. While the Department has moved to update pathogen standards for poultry products, standards for beef and pork products are either non-existent or outdated.

Can you commit to me that your Department will update beef and pork pathogen standards?

*Answer.* The Food Safety and Inspection Service (FSIS) has taken steps to collect the type of data necessary to conduct a risk assessment to ascertain whether the establishment of one or more pathogen reduction performance standards for beef and pork is likely to result in public health protection. As with the recently proposed standards for poultry products, any new proposed performance standards will be designed to achieve the Healthy People 2020 (HP2020) illness reduction goals, public

health goals that FSIS and the Department of Health and Human Services worked together to create. We continuously strive to eliminate foodborne illness, and we will continue working toward that goal by utilizing a stepwise approach grounded in a shared national objective.

USDA continues to review information on how inspection and inclusion of different lymph nodes in ground beef affects Salmonella contamination in the product, including our agencies partnering with each other (FSIS and ARS) to explore the potential public health impacts of Salmonella in lymph nodes. Findings will be incorporated into future revised slaughter guidance materials.

By May, FSIS will begin exploratory sampling of a variety of pork products, including finished products packaged and ready to be sold to the consumer, to determine which products (for example, intact parts or ground) might harbor Salmonella contamination. The results of this sampling will inform plans to collect more extensive data with which to develop public health benefit-based performance standards in alignment with HP2020 goals.

#### WILDFIRES IN CALIFORNIA

*Question.* Secretary Vilsack, California is primed for a wildfire disaster given the ongoing drought across the state. What is the Forest Service doing to be prepared to respond quickly to wildfires in California?

*Answer.* The Forest Service maintains a robust response (personnel and equipment) capability in California at levels that ensure an appropriate, risk informed and effective response to all wildland fires. The Forest Service also works extensively with our partners at CALFIRE and other local firefighting organizations, to support wildland fire management operations and meet operational objectives. Significant planning occurs throughout the year to establish response expectations for when wildfires do occur, as well as establishing roles and responsibilities for the Forest Service and our cooperators. The Forest Service works with CALFIRE throughout the fire season to pre-position assets where the risk of fire is highest. We also coordinate responsibilities for asset availability and training to be sure our response minimizes the risk to people, communities, and other high valued resources.

#### AIR TANKERS

*Question.* Secretary Vilsack, the National Defense Authorization Act of 2014 transferred seven C-130H tankers from the U.S. Coast Guard to the U.S. Forest Service for use in firefighting operations. Can you provide me an update on the transfer and retrofitting of these aircraft, and when they will be operational for fire suppression?

*Answer.* One HC-130H is expected to be in limited operation for the 2015 fire season. The aircraft will be equipped with a Modular Airborne Fire Fighting System (MAFFS). A second HC-130H may be available later in 2015, depending on Air Force maintenance schedules. This aircraft will be used for flight testing and evaluation only and will not be equipped with a MAFFS unit. Ownership for both aircraft will be retained by the Coast Guard until all required maintenance is completed and a retardant delivery system is installed. Once that is completed ownership will be transferred to the Forest Service.

The first aircraft with the new gravity retardant delivery system installed is expected in 2017 and the second in late 2017. Three more are expected in fiscal year 2018 and the final two in fiscal year 2019.

#### ANTIMICROBIAL RESEARCH

*Question.* Secretary Vilsack, I am pleased to see that your Department has requested increased funding to collect data on antibiotic use patterns and antibiotic resistance. This data will be critical for monitoring public and animal health.

What type of studies and surveys does your Department have planned?

*Answer.* If funding is provided as requested in the 2016 President's Budget, NASS proposes to develop annual surveys for Cattle on Feed, Hogs and Pigs, and Poultry. This new data can be used to establish a baseline for these livestock and help track this growing problem. The baseline survey will do several things to respond to Antimicrobial Research or Combating Antibiotic Resistant Bacteria (CARB) problem:

- Establish data to measure the extent of the problem (broad approach);
- Strengthen the knowledge and evidence base to allow for other agencies (that do more in-depth research work) to use NASS collected data as a starting point and go forward with more probing type questions;
- Develop trend analysis;

—Check the status of CARB with annual data collection surveillance to show whether the problem is growing worse, unchanged, or improving.

NASS is working with Economic Research Service (ERS) and Animal and Plant Health Inspection Service (APHIS)—to institute an annual, national antibiotic use survey and to enhance the APHIS National Animal Health Monitoring System (NAHMS) surveys. Questions could be added to provide national, population-based estimates on antibiotic-use practices from the voluntary NAHMS survey. In addition, a sufficient number of operations could be sampled and tested for the presence of zoonotic pathogens (e.g., Salmonella, Campylobacter) and commensals (e.g., Enterococcus, E. coli) to provide national, population-based estimates on prevalence and antimicrobial resistance in these organisms.

ERS is collaborating with other USDA science and program agencies through the USDA Antimicrobial Resistance Action Plan Committee to examine the economic implications of efforts to combat antimicrobial resistance. ERS research draws on data from the Agricultural Resource Management Survey (ARMS) to examine how antibiotics are used in livestock production; to estimate the effects of antibiotics used for disease prevention and growth promotion on farm-level costs and productivity; and to identify alternative production practices used on operations that eschew the use of antibiotics for those purposes. In fiscal year 2016 analysis from the farm-level ARMS will explore the extent of use by livestock species, stage of production, and purpose, as well as the impact of use on growth and recent policy issues.

*Question.* Do you have the cooperation from livestock producers necessary to make these surveys and studies successful?

*Answer.* NASS has contacted the industry for broilers, cattle on feed, and hogs & pigs. NASS needs to do more outreach to get more cooperation from the industry, however, those contacted realize the importance of collecting this information. NASS realizes that without industry cooperation these surveys will not be a success.

*Question.* Secretary Vilsack, the Food and Drug Administration (FDA) is implementing new policies to eliminate non-therapeutic antibiotic use in agriculture and to move antibiotics under veterinary oversight.

What additional steps can your Department take to educate veterinarians on these new FDA policies and to improve antibiotic stewardship in agriculture.

*Answer.* USDA will continue to conduct outreach as appropriate, in coordination with FDA, to ensure veterinarians are aware of FDA's policies.

#### SPECIALTY CROP PEST PROGRAM

*Question.* Secretary Vilsack, I am deeply concerned that your Department proposed to cut the Specialty Crop Pest Program. California continues to battle many agricultural pests and diseases, and there is increasing risk that new pests and diseases will be introduced to the state via international commerce. In fact, the Glassy Winged Sharpshooter, a devastating pest to grapes, was found in Marin County this month.

What additional steps can your Department take to combat agricultural pests and diseases like the Glassy Winged Sharpshooter?

*Answer.* I certainly recognize your concern about the risks posed by invasive pests and diseases to California agriculture. I can assure you that preventing the entry of pests and diseases into the United States and detecting any new introductions early remains one of USDA's highest priorities.

In addition to using appropriated funding, APHIS is using funding provided under Section 10007 of the 2014 Farm Bill to enhance early detection and emergency response efforts for plant pest and disease management and disaster prevention programs. In developing the spending plan each year, APHIS seeks suggestions from States and U.S. territories, universities, other Federal agencies, nongovernmental organizations, private companies and tribal organizations for projects that would provide a direct and meaningful impact in managing pests and diseases, as well as disaster prevention.

In fiscal year 2014, APHIS funded 382 suggested projects across the United States, as well as in Guam and Puerto Rico, with 30 projects in California. The projects in California included surveys for exotic pests that attack citrus, tomatoes, nursery stock, and a variety of other specialty crops, training for detector dogs to find exotic pests in mail and cargo, as well as projects focused on best practices for nurseries in preventing the introduction and spread of diseases like Phytophthora ramorum and other invasive pests. These efforts allow APHIS and State partners to continue strengthening protections against agricultural threats. APHIS will release the fiscal year 2015 spending plan in spring 2015.

In regard to the recent detection of a live glassy-winged sharpshooter (GWSS) on a nursery shipment that was being unloaded in Marin County, county inspectors or-

dered all of the plants to be reloaded and then sealed the trucks. The trucks returned to Ventura County the next morning. The California Department of Food and Agriculture (CDFA) and Marin County officials placed additional traps at the location where the insect was found and will continue to monitor the area for a month. Through this program, APHIS, CDFA, and the grape industry work to prevent the spread of GWSS into the major grape-producing counties of California. The program will continue using proven regulatory protocols and inspections to prevent GWSS from expanding its range. The Agency's fiscal year 2016 budget proposes a decrease for the GWSS program to encourage cooperators to put additional resources into this program that benefits them. If cooperators are able to devote additional resources, programs will continue to operate at the same level as in fiscal year 2015. If cooperators cannot increase contributions, APHIS and CDFA will prioritize the remaining funds to address the highest risk threats.

#### ANIMAL WELFARE ACT

*Question.* Secretary Vilsack, the Inspector General (IG) published an audit in December that found troubling inconsistencies in enforcement of the Animal Welfare Act. This follows a 2010 IG audit that identified similar problems. I am also concerned that your Department is not fully utilizing the existing enforcement authorities provided in the Animal Welfare Act, such as seeking a temporary restraining order or injunction against violators who place animals in extreme danger.

What additional steps can your Department take to improve enforcement of the Animal Welfare Act?

*Answer.* USDA uses all available enforcement options to ensure licensees and registrants are appropriately penalized for their violations of the Animal Welfare Act (AWA). USDA places special emphasis on the investigation and enforcement of cases where alleged animal suffering has occurred or when the lack of proper handling causes concern for the safety of the animal.

Cases warranting formal prosecution may be resolved by license suspensions, license revocations, issuing cease-and-desist orders, imposing civil penalties, or combinations of these penalties. Concurrently, APHIS continues to exercise its authority to confiscate animals that are suffering when a licensee or registrant fails to comply with the AWA regulations and standards. Since 2010, the Agency has confiscated 218 animals using this authority. When appropriate, USDA may also work with licensees to move their animals to another facility when a licensee is unable to meet the animal welfare standards or can no longer provide appropriate animal care. In doing so, a licensee may agree to the suspension or revocation of their license or permanent disqualification from engaging in AWA-regulated activities. For example, in fiscal year 2013, APHIS issued 22 settlement agreements that resulted in the placement of more than 2,900 animals as well as sanctions involving AWA licensing. USDA undergoes a review process prior to issuing a license or registration. USDA will deny or terminate a license if the applicant or licensee is determined to be unfit and attempting to conduct business contrary to the purposes describe in the AWA.

Where circumstances warrant, USDA has issued penalties at or near the \$10,000 maximum authorized, particularly in cases involving research facilities and carriers (neither of which are subject to license suspension or revocation). Beyond seeking higher monetary penalties, we have pursued administrative litigation against chronically non-compliant entities, allowing us to seek strong sanctions.

In November 2014, the Department of Justice revised the United States Attorneys' Manual to designate a central coordinating division to support USDA cases related to the welfare of animals regulated under both the AWA and the Horse Protection Act. As a result of this new collaborative relationship, USDA is better positioned to use enforcement authorities such as temporary restraining orders or injunctions to protect the lives of animals facing immediate danger while other administrative or legal actions are proceeding against a violator.

#### ADEQUACY OF THE THRIFTY FOOD PLAN

*Question.* At a time when more than one in six Americans struggle to put food on the table, it is imperative that our nutrition assistance programs provide access to an adequate diet. According to the Institute of Medicine (IOM), however, current Supplemental Nutrition Assistance Program (SNAP) benefit levels based on the thrifty eating plan are insufficient in most circumstances and leave many households hungry by the end of the month. Research also demonstrates that, while it is possible for many households to shop for healthy foods using this budget, it requires an additional 6 hours per week, which is especially challenging for low-income families.

How does USDA's 2016 budget aim to address the insufficiency of current SNAP benefit levels based on the thrifty eating plan to provide access to adequate nutrition?

*Answer.* FNS is currently addressing the sufficiency of SNAP benefit levels through our annual research budget by initiating the research that was recommended by the Institute of Medicine expert panel that looked at SNAP benefit adequacy.

Last fall, FNS awarded a contract to an external organization to conduct a study that will assess the individual, household, and the environmental factors that limit adequacy of the SNAP allotment. This study is developing a new data collection to survey SNAP participants to determine these factors. The survey includes questions about cooking skills, shopping patterns, nutritional literacy, financial literacy, time available for preparing food, and other constraints. The final report is expected in 2017.

In addition, before the end of fiscal year 2015, FNS anticipates awarding another contract to an external organization to determine whether the current parameters of the SNAP eligibility determination and benefit level calculations adequately match the real costs that low-income households have in regards to household budgets and food expenditures. This study will use existing data to examine spending patterns among low-income households to assess whether current SNAP parameters are based on realistic assumptions regarding household expenditures for food, shelter, medical care and dependent care. The final report is expected in 2016.

#### ASSISTANCE TO DROUGHT IMPACTED COMMUNITIES IN CALIFORNIA

*Question.* What additional steps can your Department take to accommodate drought impacted communities in California, where families are reporting spending as much as 7 percent of their SNAP benefits on water because fresh drinking water is no longer available in their home?

*Answer.* Feeding low-income families across the United States is at the heart of USDA's mission. The USDA nutrition assistance programs, such as the Supplemental Nutrition Assistance Program (SNAP) and The Emergency Food Assistance Program (TEFAP), are designed to respond to needs such as those resulting from the drought.

SNAP is USDA's primary nutrition assistance program to address the needs of those experiencing economic difficulties. SNAP is designed to respond to deteriorations in local economic conditions, as more people lose jobs they become eligible for the program.

For example, in March 2015, FNS awarded an Employment and Training Grant in the amount of \$12 million to Fresno County Department of Social Services to offer multiple career-driven services, including education, job training, support services, subsidized and unsubsidized employment, retention services, ongoing case management, and financial incentives for clients for milestone achievements. The grant will provide SNAP recipients with new or better skills to improve their employment opportunities. This would also help residents receiving SNAP who have been displaced because of the drought.

TEFAP is also designed to meet emergency food needs for those experiencing hard economic times. Through TEFAP, food and administrative funds are made available by USDA to States. States provide the food to local agencies that they have selected, usually food banks, which in turn, distribute the food to soup kitchens and food pantries that directly serve the public. Each TEFAP State has the discretion to allocate TEFAP resources to participating recipient agencies within the State as it sees fit. Such TEFAP resources allocated within the State are used to help individuals in need, including individuals impacted by emergency situations, such as a drought.

Additional information on steps the Department is taking to accommodate drought impacted communities in California is provided for the record.

USDA made \$76.7 million available through TEFAP to food banks in the State of California to help families, including those that may have been economically impacted by the drought. In fiscal year 2014, California was offered \$35.2 million in food and \$6.6 million in administrative funds through TEFAP, based on a Federal funding formula which accounts for the State's share of national poverty and unemployment. Additionally in fiscal year 2014, California received \$34.9 million of USDA bonus (i.e., market support) purchases of USDA Foods. In fiscal year 2015, USDA offered California \$42.8 million in foods and \$6.5 million in administrative funds through TEFAP, based on the above referenced funding formula. Additionally in fiscal year 2015, \$14.2 million worth in bonus purchases made by USDA have been received in California year-to-date.

In 2014, USDA worked with the California Department of Education to target efforts to expand the number of Summer Food Service Program meal sites. Over 3,600 summer meal sites operated in California in 2014. Also in fiscal year 2014, USDA, in collaboration with the California Department of Education, created a goal to establish 600 summer meal sites in drought stricken areas. The agency exceeded this target and by summer's end had 725 sites in the region. In 2015, FNS will continue to work with the California Department of Education and other states to ensure summer meals are available in areas affected by the drought.

In 2014, USDA participated on the California Drought Task Force as an advisor on USDA nutrition assistance resources available and will continue to participate on the Task Force in 2015, as needed.

USDA continues to work with the California Departments of Social Services, Education and Public Health as well as California's food banks to provide referrals and information on FNS programs such as eligibility, how and where to apply, and meal sites and hours of operation for the Summer Food Service Program, so that children up to the age of 18 can get a free meal.

#### MILITARY FAMILIES RECEIVING SNAP BENEFITS

*Question.* The national food bank network Feeding America estimates in their 2014 Hunger Study that 20 percent of the 15.5 million households receiving food assistance from them nationally include someone who has previously served in the military, and roughly 4 percent of households include someone currently serving in the military. In San Diego, roughly 10 percent of households seeking food assistance from the Feeding America Network contain an active duty military member.

There are also food pantries on military bases across the country. The 2015 Military Compensation and Retirement Modernization Commission (MCRMC) report cites estimates from USDA that in fiscal year 12, between 2,000 and 22,000 military service members received SNAP benefits. Estimates of SNAP usage by military members vary widely because states that administer these benefits are not required to collect data on the actual number of active-duty service members in households receiving SNAP.

Clearly there is a need for food assistance among military families, but these numbers indicate that military families who need Federal food assistance may not be fully served by the program. The same MCRMC report recommends ending the military's Family Subsistence Allowance (FSA) program and favors the enrollment of needy military families in SNAP, but these families continue to face barriers accessing SNAP. Namely, military families who live off base are reviewed differently than military families who live on base in terms of how their military-provided housing is recorded when determining SNAP eligibility and benefits. In addition, military families could face additional barriers to accessing SNAP depending on their station location under recent proposals to convert SNAP into a block grant program.

In order to adequately plan for the SNAP program, how does USDA's fiscal year 16 budget assess the number of military households currently enrolled in SNAP and the number of military households who are potentially eligible for SNAP?

*Answer.* While military families not stationed overseas are eligible to receive SNAP, few do, because their incomes at most ranks make them ineligible for benefits. While data is limited, the best estimates suggest only about one or 2 percent of individuals currently on active duty receive SNAP. Our SNAP budget projections are based on total expected caseload and benefit levels, which includes any military families that are eligible to receive SNAP and choose to participate in the program. FNS expects to have sufficient funds to serve any military households that are eligible and wish to receive SNAP benefits.

#### FOOD INSECURITY IN MILITARY HOUSEHOLDS

*Question.* How does USDA's fiscal year 16 budget make an effort to address food insecurity in military households and increase their access to SNAP?

*Answer.* SNAP continues to be a vital nutrition assistance support program for low-income households, including those with eligible military service men and women, and veterans. In addition, SNAP provides employment and training (E&T) services to participating unemployed or under-employed individuals, including veterans, that enhance or supplement existing services. USDA provides \$90 million to States for the cost of administering and operating a SNAP E&T program each year and reimburses States for 50 percent of additional administrative costs and participant expenses associated with these programs. States can design their E&T programs to meet the unique needs of targeted populations, such as veterans and those experiencing homelessness.

Under SNAP rules, able-bodied adults without dependents (ABAWDs) are required to work or participate in a work program at least 20 hours a week in order to receive SNAP for more than 3 months within a 36-month period. The ABAWD population invariably includes some of the most at-risk veterans. In order to serve this group, USDA allocates a portion of an additional \$20 million to each State that pledges to provide qualifying E&T services to all at-risk ABAWDs so that they may continue to receive SNAP benefits while searching for work, participating in training, or gaining work experience.

Lastly, USDA's fiscal year 2016 budget request includes \$25 million in additional SNAP E&T grants to help States to offer targeted employment and training services to ABAWDs. This additional funding will ensure that ABAWDs continue to receive nutrition assistance while improving their skills and preparing to enter the labor market.

#### SUMMER ELECTRONIC BENEFIT TRANSFER (EBT) DEMONSTRATION PROJECTS

*Question.* More than one in five American children is in a household struggling with hunger, an astonishing number. Child hunger is often most prevalent in the summer when school is out of session.

Despite the impressive progress that USDA continues to make in expanding access to the Summer Food Service Program (SFSP), only 2.1 million children were served in July 2003, which is only about 14 percent of those who received free or reduced-price school meals during the previous school year.

One of the most promising programs to supplement the SFSP—especially for rural areas like the drought-affected Central Valley, where access to summer sites is especially difficult—is the Summer Electronic Benefit Transfer (EBT) demonstration projects piloted by USDA. The evaluations of this program to provide nutrition assistance in the form of EBT cards has proven to dramatically reduce summer hunger, including reducing the most severe forms of child hunger by approximately one third. Moreover, this program has very low administrative costs, and it benefits local jobs and economies through grocery spending.

Given the existing pilot data proving the strength of summer EBT, as well as new academic research about the lifelong impact of even one incidence of hunger, how does USDA propose to scale up the summer EBT program so that it is part of our national response to the summer child hunger crisis?

*Answer.* While the school meal programs serve about 21 million low-income children each school day, summer meal programs, including the Summer Food Service Program and the National School Lunch Program Seamless Summer Option, reach only about 3.7 million (or about 16 percent) of these children in the summer—a time of increased food insecurity for children.

Summer Electronic Benefit Transfer for Children (SEBTC), funded by Congress in 2010 as a demonstration project, has shown clear results in reducing very low food security among children, the most severe form of food insecurity. The SEBTC evaluation showed it reduced the most severe form of childhood hunger by a third. It also showed that SEBTC can reach a significant proportion of children eligible for free and reduced-price school meals. Across the 14 pilot sites, SEBTC reached between 30—75 percent of children eligible for free and reduced-price meals in the summer. Furthermore, SEBTC children ate more healthfully. They ate about 13 percent more fruits and vegetables, 30 percent more whole grains, and 10 percent more dairy.

Congress provided \$16 million to continue these demonstration projects during the summer of 2015. FNS offered the 10 grantees that previously administered the SEBTC pilots the opportunity to continue providing benefits to children previously served and to expand the program in rural areas. Eight grantees continued their participation in SEBTC for summer 2015: Cherokee Nation, Chickasaw Nation, Connecticut, Delaware, Michigan, Missouri, Nevada, and Oregon. Two grantees from previous years, Texas and Washington, declined participation due to prohibitive logistical constraints or implementation barriers based on the late notice of funding. Because of uncertainties in receiving a final 2015 budget, FNS could not inform sites until late spring that they would receive summer funding. Combined with funds remaining from previous years, FNS was able to provide nearly \$23 million to these eight grantees to continue and expand the program for the summer of 2015.

USDA is requesting an additional \$50.9 million in fiscal year 2016, for a total of \$66.9 million to continue SEBTC demonstration projects. Funding in fiscal year 2016 will allow FNS to continue the program in several States, benefitting as many as 200,000 families.

*Question.* How, if at all, are any of these additional investments targeted toward California, home to more poor children and homeless children than any other state?

*Answer.* California was not one of the original 10 grantees selected to participate in the SEBTC demonstration project. Due to limited additional funding, FNS has been unable to solicit additional requests for proposals allowing new States to participate.

However, FNS has provided targeted technical assistance to California for the past two summers in order to increase participation in the USDA summer meal programs. We saw increases in meals served in both summer 2013 and 2014, with almost 825,000 more meals in 2014 than the summer before (5.75 percent increase). California continues to build on this success and aims to increase the number of meals served by 5 percent in summer 2015. And, as noted in our response on the question related to drought, we are also focusing additional attention on drought impacted areas of the state.

---

#### QUESTIONS SUBMITTED BY SENATOR PATRICK J. LEAHY

##### BUDGET RECONCILIATION

*Question.* Do you share my concerns that a reopening of the Farm Bill as part of budget reconciliation would be devastating to the work your Department has been doing to implement the new Farm Bill authorities and provide certainty to program participants, crop insurance recipients, SNAP recipients, and agricultural producers who are just now going into the 2015 crop year and making sign up decisions?

*Answer.* The new Farm Bill builds on historic economic gains in rural America over the past 5 years, while achieving meaningful reform and billions of dollars in savings for the taxpayer. It has allowed USDA to achieve record accomplishments on behalf of the American people, while providing new opportunity and creating jobs across rural America. It has enabled USDA to further expand markets for agricultural products at home and abroad, strengthen conservation efforts, create new opportunities for local and regional food systems and grow the biobased economy. It has provided a dependable safety net for America's farmers, ranchers and growers and maintained important agricultural research, and ensure access to safe and nutritious food for all Americans.

The Administration strongly supports the Supplemental Nutrition Assistance Program (SNAP) and other critical programs that reduce hunger and help families meet their nutritional needs. To ensure these needs are met, the budget includes mandatory funds to fully support estimated participation levels for the Supplemental Nutrition Assistance Program (SNAP). SNAP is the cornerstone of the Nation's nutrition assistance safety net, touching the lives of millions of low-income Americans, the majority of whom are children, the elderly, or people with disabilities. SNAP kept over 5 million people, including nearly 2.2 million children, out of poverty in 2013.

Although the Farm Bill included several reforms to the Federal crop insurance program; there remain further opportunities for improvements and efficiencies. The President's 2016 budget includes two proposals to reform crop insurance, which are expected to save \$16 billion over 10 years. This includes reducing subsidies for revenue insurance that insure the price at the time of harvest by 10 percentage points and reforming prevented planting coverage, including adjustments to payment rates. These reforms will make the program less costly to the taxpayer while still maintaining a quality safety net for farmers.

##### AGRICULTURAL RESEARCH SERVICE

*Question.* I understand that the Agricultural Research Service has financial needs relating to the upkeep of its facilities. While I want the Service to have the resources it needs to maintain its facilities I am concerned about ARS potentially shifting funds from existing programming lines to address this need. Can you provide the Committee with more details about the needs of its facilities and provide reassurance that ARS is not pulling back resources from partnership programs to fund this work?

*Answer.* ARS annually requests funding specifically for the repair and maintenance (R&M) of often dilapidated facilities to ensure that no funds are pulled back from research in order to fund R&M work. In fiscal year 2015, ARS requested and allocated \$20 million of a \$1.13 billion appropriation to carry out the research mission of the agency for repair and maintenance. This is less than 2 percent of its appropriated budget.

The fiscal year 2016 budget request includes an increase of \$20 million to help address the backlog and extend the life span of ARS research laboratories and facilities, provide opportunities for longer term savings, and ensure the capacity to con-

duct safe, quality research. These funds will be distributed on a priority basis across the agency's entire facility inventory. The cost for most of these repair and maintenance projects ranges from \$50,000 to \$500,000.

The ARS facility infrastructure is valued at more than \$3.7 billion, with many of these facilities established in the 1950s and 1960s. The backlog of repair and maintenance (R&M) needs exceeds \$320 million for work such as the repair or replacement of: HVAC, electrical, plumbing, roof, building envelope, site utility system, fire protection system, and other safety systems. Many of these systems and items have reached the end of their service life and no longer meet compliance or safety requirements.

#### RURAL HOUSING

*Question.* In many rural communities, the only available source of affordable rental housing is funded through the Section 515 Rural Rental Housing Loan Program. Today, nearly 400,000 of America's most vulnerable families live in housing financed under Section 515 and nearly 94 percent of Section 515 tenants earn very low incomes.

However, after years of significant budget cuts for the program, in 2012, the Department halted financing the construction of new rental housing. Current funding for the Section 515 Rural Rental Housing Direct Loan Program is used only for the much needed rehabilitation and maintenance of the existing portfolio.

How does the Department's proposed budget assist the rural Americans who are not looking to become homeowners, but are in need of an affordable place to live with their families?

*Answer.* The 2016 budget seeks to assist rural Americans in need of rental housing in a number of ways. First, it provides rental assistance to support more than 250,000 rural residents in need of safe, decent and affordable housing. Second, it increases funding in the Section 515 and MPR program to help preserve and revitalize Rural Development's existing rental housing portfolio. Third, it proposes to increase funding in the Section 515, Section 538 Guaranteed, and Rental Assistance programs for the construction of additional affordable housing, particularly in persistent poverty areas such as Strike Force and Promise Zones that are most in need of that housing. And fourth, the 2016 budget proposes to extend housing vouchers to residents of Section 515 properties with maturing mortgages, to the extent possible, so eligible tenants in those properties will be given the same protection from potentially significant rent increases that is currently provided to tenants in Section 515 properties prepaying their mortgage.

*Question.* Unfortunately, funding for new construction of rental housing in rural America is not included in this budget. For rural communities facing housing shortages and shrinking state budgets, what role do you see the Department having in addressing the need for additional units of affordable rental housing in rural America, if not through funding?

*Answer.* The 2016 budget includes funding for new construction in the Section 515 program, as well as in the Section 538 and Farm Labor Housing programs. In recent years, the Department has focused on using its Section 515 program to help meet the need to revitalize its existing housing portfolio, due to the age of the 515 portfolio and the expected preservation needs. However, the fiscal year 2016 budget includes some funding that would help provide additional affordable rental housing in persistent poverty areas where the housing needs are greatest.

Rental Assistance would also be available to support tenants in that new housing. The Section 538 guaranteed program provides another avenue for new construction of affordable housing; nearly all of the program's housing includes Low Income Housing Tax Credits, which ensures that only low income residents qualify for the housing.

#### FOOD SAFETY MODERNIZATION ACT

*Question.* I am very worried about the potential impact the new FDA food safety regulations could have on our small farms in Vermont. That is why I pushed for the authorization of the new Food Safety Outreach Program in FSMA, because your USDA staff and extension agents are best suited to help small and mid-size farms and small local food processing facilities comply with the new food safety regulations. I believe that if we do not educate before we regulate, we are just setting the FDA up for failure.

Can you tell me how USDA will use the \$2.5 million in fiscal year 15 funds to help farmers comply with this onslaught and burden of potential fees, paper work, and confusing rules? And do you think there are enough resources being allocated

to help our produce farmers and those involved with any value-added or on-farm processing to understand these complex new rules?

*Answer.* The U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture's National Institute of Food and Agriculture (NIFA) have joined in a collaborative partnership to administer a competitive grant program designed to develop a comprehensive food safety training, education and technical assistance program for those affected by the Food Safety Modernization Act (FSMA). Specifically, the program will address the needs of owners and operators of small and medium-sized farms, beginning farmers, socially disadvantaged farmers, small processors, or small fresh fruit and vegetable merchant wholesalers. Although these entities will be directly impacted by new FSMA guidelines, many lack access to the resources needed to implement those guidelines. Both FDA and USDA recognize that food safety training, education, and technical assistance for these entities are critical to ensuring awareness and compliance with new produce safety standards and preventive controls for human and animal food proposed under FSMA future appropriation.

The joint program will award grant funds that enable awardees to establish a National Coordination Center for Food Safety Outreach and four Regional Food Safety Training Centers (Regional Centers). The National Coordination Center will provide overall leadership for support and coordination of the Regional Centers, while ensuring that food safety training, education, outreach, and technical assistance across the entire program are consistent with FSMA guidelines. Each Regional Center will lead, manage, and coordinate the regional development and implementation of food safety training, education, outreach and technical assistance programs for the intended audiences. Both FDA and NIFA will work with Regional Centers and the National Coordination Center to help establish and maintain an effective and sustainable program that will meet the ongoing needs of intended audiences affected by new FSMA guidelines.

While the \$2.5 million appropriated in fiscal year 15 will enable NIFA, in coordination with FDA to begin building an infrastructure that will support a national food safety training, education, extension, outreach, and technical assistance system and provide significant opportunities for partnerships with stakeholder groups that include produce farmers and those involved with value-added or on-farm processing, additional funds, such as the \$2.5 million increase requested in the President's 2016 budget, will strengthen and further expand the infrastructure in ways that will benefit multiple stakeholder groups.

#### NATIONAL ORGANIC STANDARDS BOARD RECOMMENDATIONS

*Question.* This year marks 25 years since the first Organic Farm Bill was signed in to law. At the time, many in the Senate dismissed it as a niche activity that was never going to amount to much.

Organic product sales in the United States are now valued at \$35 billion a year and have posted double-digit growth year after year after year. The only way this growth can continue and our farmers can benefit, is if we can assure consumers that the USDA Organic logo stands for something strong. There is a lot of confusion among consumers today and one area of particular interest to me is surrounding regulations on how animals are raised and their access to pasture. This is a basic tenet of organic production. Livestock must have access to fresh air and sunshine whenever possible.

In 2011 the National Organic Standards Board put forward a recommendation that the Department move forward with a rulemaking process laying out the standards for livestock healthcare and living conditions, including access to the outdoors.

What assurances can you give me that the Department is moving forward to finally respond to the recommendations put forth by the National Organic Standards Board?

*Answer.* The National Organic Standards Board (NOSB) has provided over 200 recommendations regarding the National List of Allowed and Prohibited Substances as well as over 150 recommendations concerning other aspects of the USDA organic standards. The Department has implemented 222 of the National List recommendations and 127 of the general organic standards recommendations and incorporated them into the USDA organic regulations. USDA plans to respond to the outstanding National List recommendations from October 2014 and NOSB recommendations regarding the prohibition of sodium nitrate in organic production within the next 2 years. An additional 13 recommendations will be addressed through current initiatives, which include rulemaking on origin of livestock, aquaculture, pet food, apiculture, and animal welfare. USDA is also establishing a Hydroponics/

Aquaponics Task Force that will report to the NOSB regarding their Greenhouse recommendation.

#### USDA WILDLIFE SERVICES

*Question.* The USDA Animal Plant Health Inspection Service (APHIS) is the charged with, among other things, protecting agriculture and fisheries from nuisance and invasive species. For many years APHIS was the lead agency in controlling the double crested cormorant (cormorants) populations on Lake Champlain in Vermont and New York as well as across the region including the upper Saint Lawrence River, the Finger Lakes of New York, Lake George and other large water bodies. Cormorants are considered a nuisance species in this region and peer reviewed scientific studies have shown that in some cases cormorant predation can have a negative impact on commercial and sportfish stocks. The birds also have an easily observed devastating impact on public and private property where they roost and nest.

In recent years, however, APHIS cormorant control activity on Lake Champlain has been greatly reduced and this correlates with an increase in cormorant numbers. I am hearing from concerned Vermonters that in the time since the USDA Wildlife Services has cut back on resources being directed to reduce cormorant numbers on Lake Champlain we have seen a dramatic spike in this migratory birds population, which has an easily observed negative impact on terrestrial habitat and many feel is also having a severely detrimental effect on game fish populations.

What amount of funds does the USDA propose to allocate to cormorant control activities on Lake Champlain in New York and Vermont in fiscal year 16?

*Answer.* USDA plans to spend \$15,000 in fiscal year 2016 to reduce the impact of the cormorant population in the Lake Champlain region.

*Question.* Will this funding be sufficient to enable APHIS to control cormorant populations on Lake Champlain at a level that mitigates the worst damage to private and public property and to commercial and sportfish stocks of Lake Champlain?

*Answer.* If USDA funding is not sufficient to fully address the issue, APHIS could provide additional cormorant control on a requested basis if cooperative funding were made available through other Federal or State sources, grants, or agreements with non-government entities.

#### TREE AND FOREST PESTS

*Question.* When I look at the request in your budget for the Animal Plant Health Inspection Service (APHIS) Tree & Wood Pests work and another massive cut in its funding I am shocked. While they may not get the sort of news coverage that the forest fires out west often do, the invasive pests in our forests are a critical threat to our forests and our economy.

Despite the increasing risk and impacts, funding for the "Tree and Wood Pest" account has been reduced by nearly 30 percent since fiscal year 11. The President's budget now proposes cutting the program further, from \$54 million to \$46 million. Even at current funding levels for this budget account, APHIS cannot maintain efforts to curtail spread of insects that are already established, much less respond to new threats every year.

With the funding level requested in your budget will the Department continue to focus on the eradication of the Asian longhorned beetle that threatens Vermont's forest industry and our sugarmakers? And with this proposed \$8 million reduction in spending what work is the Department proposing to cease related to tree and wood pests?

*Answer.* The Asian long-horned beetle (ALB) is a serious, invasive tree pest that threatens roughly 30 percent of U.S. trees that are potential hosts. APHIS continues to focus on the eradication of ALB. Since APHIS began the ALB eradication program in 1996, the Agency has successfully eradicated infestations from Jersey City, Middlesex County, and Union County, New Jersey; Islip, Staten Island and Manhattan, New York; and Boston, Massachusetts. In addition to these northeast States, APHIS has also successfully eradicated ALB from an infestation in Chicago, Illinois. The Agency is currently conducting ALB eradication activities in northeast forests in New York and Massachusetts, as well as in Ohio.

APHIS is proposing decreases to two areas of the Tree and Wood Pests program: the ALB eradication program and emerald ash borer program. These proposed decreases are to allow for more equitable sharing of costs between the Federal government and those who benefit from these important programs. If cooperators are able to increase their contributions to the programs, they will continue to operate at their current levels. If contributions to the programs do not increase, APHIS would

focus available resources on preventing the spread of pests and diseases to new areas.

---

QUESTIONS SUBMITTED BY SENATOR TAMMY BALDWIN

MARGIN PROTECTION PROGRAM FOR DAIRY

*Question.* As we look back at the first round of signups for the new Dairy Margin Protection Program, we saw just over half of the dairy farmers in the country sign up, and about 55 percent of those bought up to higher levels of coverage beyond the base, catastrophic level. Wisconsin's sign up percentages were only slightly better than the national average. What is USDA planning to do to make it easier for farmers to sign up for 2016?

*Answer.* The Margin Protection Program for Dairy (MPP-Dairy) is a significant change for dairy producers that were accustomed to the Milk Income Loss Contract (MILC) program, since MILC did not require fees or premiums to be paid. The first year enrollment for MPP-Dairy compares very favorably to the initial enrollments for other risk protection programs such as initial crop insurance offerings.

USDA will build on our successful outreach efforts including partnering with Extension Services to ensure all dairy producers are informed about the coverage options provided under MPP-Dairy. Current participants also will receive a reminder letter providing them with their previous coverage options and applicable forms that can be mailed back to the Farm Service Agency (FSA) county office, along with their applicable fees, for continuous coverage into 2016 without requiring another trip to the local FSA office.

*Question.* One of the things that I am hearing from back in Wisconsin is that it would be very helpful for USDA to allow dairy cooperatives to deduct the premiums for the MPP program from their producers' monthly milk checks, and submit the payments to USDA on their behalf. Currently, farmers' options are to pay their MPP premiums in one lump-sum annual payment or two annual payments. That can result in some big payments and cash flow challenges that might deter some farmers from participating fully in the program. This may be particularly true for next year, because prices are much lower than during the last sign up, so farmers have less cash on hand. Will USDA be modifying the rules for the 2016 sign up to allow for monthly payments of MPP premiums through their cooperatives?

*Answer.* USDA supports providing additional MPP-Dairy premium payment options to provide more flexibility to producers. Even in the first year, FSA provided an initial option that allowed producers to pay premiums later in the year after coverage had begun and back loaded the premiums so that only 25 percent was due initially. Even with this additional producer friendly option, 60 percent of producers paid the premium in full in 2014. With respect to cooperatives, there is no prohibition on another party paying the fees on behalf of a producer. A private arrangement between a cooperative and a producer would be possible now as long as the cooperative met the same deadlines for premiums being paid.

We understand that cooperatives may not be interested in assuming the role of aggregating premiums and potentially prepaying for their members. We are therefore exploring the possibility of allowing monthly payments of premiums either directly or through cooperatives. We believe this would be a favored enhancement to the program that would increase participation. While this option will not likely be available during enrollment, we are exploring the option in some form for the 2016 premiums later this year.

*Question.* As we think about the next sign up, one thing that would be very helpful is to have data about what decisions farmers made for 2015. Currently, we know what percentage of farmers in every state signed up, and what percentage bought up to higher levels of coverage. What we don't know is a breakdown of what buy up coverage levels they purchased. A farmer that buys up has an option of purchasing protection for a \$4.50 margin protection level, all the way up to an \$8 coverage level. This information would be extremely helpful information to have. Is that something you could provide to us in the near future?

*Answer.* The coverage level breakdown for 2015 MPP-Dairy is available at [http://www.fsa.usda.gov/Internet/FSA\\_File/ta\\_2\\_mpp\\_ct\\_ops\\_by\\_cvge\\_lev.pdf](http://www.fsa.usda.gov/Internet/FSA_File/ta_2_mpp_ct_ops_by_cvge_lev.pdf). The information is provided below for the record.

[The information follows:]

TABLE 2—COUNT OF DAIRY OPERATIONS BY COVERAGE LEVEL FOR 2015 MARGIN

State	\$4.00	\$4.50	\$5.00	\$5.50	\$6.00	\$6.50	\$7.00	\$7.50	\$8.00	Total
Alabama	14	.....	1	.....	1	.....	.....	.....	.....	16
Alaska	2	.....	.....	.....	.....	.....	.....	.....	.....	2
Arizona	46	.....	.....	.....	33	1	.....	1	.....	81
Arkansas	24	.....	4	.....	13	19	2	.....	.....	66
California	794	5	70	14	168	42	1	18	.....	1,112
Colorado	59	.....	4	1	15	9	.....	1	4	93
Connecticut	17	.....	1	.....	10	48	3	11	.....	90
Delaware	15	.....	.....	.....	1	4	.....	.....	.....	20
Florida	57	.....	.....	.....	19	5	.....	1	.....	87
Georgia	99	.....	1	3	36	21	6	17	3	186
Hawaii	1	.....	.....	.....	.....	.....	.....	.....	.....	1
Idaho	255	2	7	5	34	41	5	10	1	360
Illinois	225	3	11	4	79	143	17	46	6	534
Indiana	273	7	8	3	57	78	4	16	8	454
Iowa	325	4	14	14	144	315	36	100	12	964
Kansas	96	2	2	5	28	45	1	14	3	196
Kentucky	165	1	7	4	80	86	7	41	3	394
Louisiana	41	.....	2	1	10	14	3	7	1	79
Maine	99	3	2	3	10	62	4	6	.....	189
Maryland	113	1	6	3	36	42	.....	14	1	216
Massachusetts	19	.....	1	3	9	34	12	33	1	112
Michigan	563	9	42	38	175	173	22	42	19	1,083
Minnesota	704	12	54	40	360	1,232	73	174	35	2,684
Mississippi	37	.....	1	3	7	13	1	2	1	65
Missouri	123	3	16	10	98	228	31	103	13	625
Montana	28	.....	6	.....	8	8	.....	1	.....	51
Nebraska	72	.....	4	4	30	38	3	3	2	156
Nevada	16	.....	.....	.....	1	2	.....	.....	.....	19
New Hampshire	13	.....	.....	.....	12	24	5	15	.....	69
New Jersey	17	.....	1	.....	6	15	3	1	2	45
New Mexico	73	.....	6	.....	51	3	.....	.....	.....	135
New York	1,037	16	75	69	371	692	39	107	28	2,434
North Carolina	87	1	3	4	27	39	.....	13	4	178
North Dakota	30	.....	1	1	6	22	.....	4	1	65
Ohio	607	2	31	22	131	170	15	54	4	1,036
Oklahoma	67	.....	.....	.....	10	17	1	4	1	100

TABLE 2—COUNT OF DAIRY OPERATIONS BY COVERAGE LEVEL FOR 2015 MARGIN—Continued

State	\$4.00	\$4.50	\$5.00	\$5.50	\$6.00	\$6.50	\$7.00	\$7.50	\$8.00	Total
Oregon .....	111	1	5	3	10	20	1	8	.....	159
Pennsylvania .....	902	12	84	53	380	570	33	111	20	2,165
Puerto Rico .....	32	2	3	.....	4	1	.....	.....	.....	42
Rhode Island .....	2	.....	.....	1	1	5	.....	1	.....	10
South Carolina .....	16	.....	.....	1	3	3	.....	4	.....	27
South Dakota .....	89	.....	4	2	30	71	6	6	1	209
Tennessee .....	148	.....	4	1	22	64	3	18	2	262
Texas .....	148	.....	15	13	101	58	7	22	7	371
Utah .....	114	.....	5	4	19	23	2	1	1	169
Vermont .....	207	1	15	7	83	203	18	54	.....	588
Virginia .....	129	.....	15	2	60	124	12	32	6	380
Washington .....	129	.....	8	12	58	83	7	12	1	312
West Virginia .....	11	.....	1	.....	8	3	1	4	.....	28
Wisconsin .....	2,635	47	198	147	973	1,544	118	294	69	6,025
Wyoming .....	2	.....	1	.....	.....	.....	.....	1	.....	4
Total .....	10,888	136	741	505	3,828	6,457	502	1,430	261	24,748

## ORGANIC RESEARCH

*Question.* The double-digit growth in annual demand for organic products in this country is very exciting. But that demand is far outpacing growth in domestic production, requiring us to import greater amounts of organic product to meet consumer needs. I believe, and I think you would agree, that these are jobs that we can and should keep in this country.

Organic research funding has also not kept pace with the growth in the organic sector. One of the great things about organic research is that much of it is useful to conventional farmers as well. For instance, research into ways to manage livestock herd health without the use of antibiotics may be an organic priority, but is has great utility for conventional livestock farmers too.

Last year, USDA's National Organic Standards Board put out a list of unmet organic research priorities, many of them to tackle issues that have either hindered domestic organic production, or would help increase domestic production of organic products.

I believe this makes the case for us to increase USDA funding for organic research, either by increasing overall funding for programs such as the Organic Transitions Program (within NIFA), or to do more organic research within the larger AFRI program. Without adequate research into the challenges facing U.S. organic farmers, it will be very difficult for us to keep pace with the exploding demand.

Wisconsin is the number 2 state in the nation for organic production and in terms of number of producers. (California is number 1). I believe there is great potential for growth in organic farms in Wisconsin, but research is key to that goal.

Could you provide for the record an accounting of how much organic research has been conducted through the AFRI program over the last 5 years, with the trend lines?

*Answer.* The information is provided for the record.

[The information follows:]

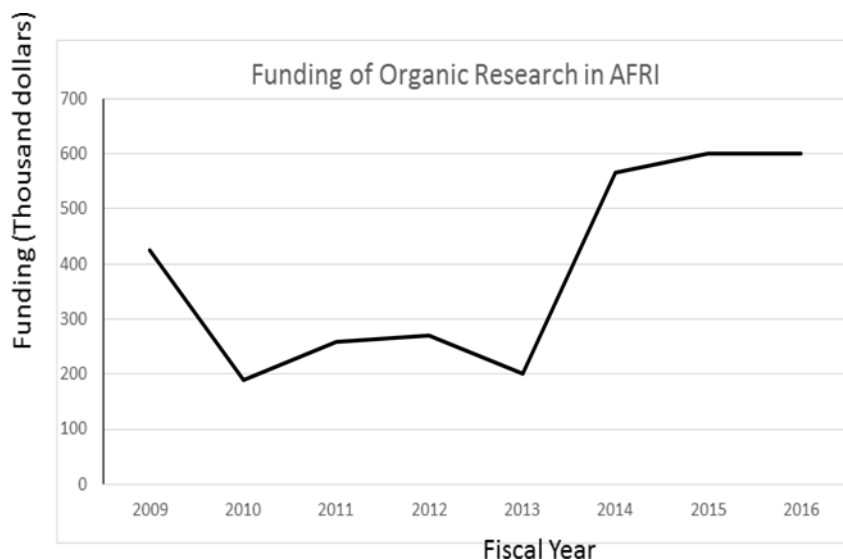
## AGRICULTURE AND FOOD RESEARCH INITIATIVE ORGANIC RESEARCH

Fiscal Year	NRI/AFRI Funding Amount (in dollars)
2009 .....	\$425,000
2010 .....	\$189,000
2011 .....	\$258,000
2012 .....	\$271,000
2013 .....	\$200,000
2014 <sup>a</sup> .....	\$566,000
2015 <sup>b</sup> .....	\$600,000
2016 <sup>b</sup> .....	\$600,000
Total, AFRI Organic Research .....	\$3,109,000

<sup>a</sup>The amount for fiscal year (FY) 2014 is the current program estimate.

<sup>b</sup>The amounts for fiscal years 2015 and 2016 are straight lined based on the fiscal year 2014 current program estimate.

TREND LINE TABLE



Awards are based on applications received and highly meritorious projects recommended for award. Therefore, fluctuations will occur.

The variation represents a decline of one grant between 2009 and 2010 followed by static funding through 2013. Due to the small sample size (i.e., one to two grants funded per year), this is a normal variation in funding for any topic.

*Question.* Can you also speak about the importance of organic agricultural research to meeting USDA's own stated goals for growing the organic sector?

*Answer.* There has been double-digit growth in annual demand for organic products. Domestic production has not been able to satisfy this demand and imports have filled this void. While it might make sense to import products that are typically not grown domestically like olive oil, coffee, coconut, banana etc., large quantities of other products like organic livestock feed and organic soybean, for instance, continue to be imported although they could be produced domestically.

In part through research, USDA is committed to assisting the organic sector. The recent 2014-2018 USDA strategic plan stresses the need for USDA to "support research and education that enables organic production." (Goal 1) This emphasis in the USDA Strategic Plan is reflected in the 2014 Research, Education, and Economics (REE) Action plan (Goal 1A) as it calls for action to "Develop more sustainable production systems for conventional, organic and low input crops ..." Goal 7 calls for the need to "Develop and share knowledge to help stakeholders implement successful organic production and marketing systems in response to growing consumer demand."

USDA, in particular NIFA and ARS, has invested in research to achieve these goals. The two major competitive programs that support organic agriculture research within NIFA are: ORG—Organic Transitions and OREI—Organic Agriculture Research and Extension Initiative. Since 2001, both programs have received 1,026 proposals of which only 186 were funded within available resources. Organic agriculture research has been encouraged in many programs within the Agriculture and Food Research Initiative (AFRI).

ARS scientists conduct organic agriculture research focused on understanding the scientific basis of biological and physical processes innate to plants, soils, invertebrates, and microbes that naturally regulate pest problems and soil fertility to improve product quality, economic competitiveness, and supply to meet increasing demand for organic products. Since 2008, ARS organic research activities have been conducted as part of the Agricultural System Competitiveness and Sustainability National Program. ARS organic research activities are coordinated with other agencies through the USDA Organic Working Group.

There is a clear need for research in organic agriculture. This work is critical to address the challenges facing producers and processors who have already adopted

organic standards as well as those who are adopting organic practices. This is widely recognized by the organic community as a major constraint to domestic production. They maintain a long list of research priorities that are essential to meet producers' needs, including, but not limited to, developing cultural practices and other allowable alternatives to substances recommended for removal from National Organic Programs' National List of Allowed and Prohibited Substances; conducting advanced on-farm crop, livestock, or integrated livestock-crop research; and strengthening of organic crop seed systems, including seed and transplant production and protection, and plant breeding for organic production, with an emphasis on publicly available releases.

#### NATIONAL ORGANIC PROGRAM SUNSET POLICY CHANGE

*Question.* One of the unique things about the organic sector is that the Organic Foods Production Act (OFPA) lays out a very rigorous process for considering what synthetic materials can be used in organic production and handling, to make sure they meet a stringent list of scientific, environmental and compatibility criteria. The National Organic Standards Board (NOSB) is in charge of this process, which has helped to build trust in the USDA organic seal.

For a synthetic material to be used in organic production, USDA's long-standing interpretation of the law has been that at least 2/3rds of the NOSB members must vote in favor of adding that material to the "National List" of allowed materials. Once on the List, the USDA policy required that the material be reviewed every 5 years and relisted again by a vote of at least 2/3rds of the NOSB. Most materials have garnered the necessary votes in order to remain approved. However, the sunset review process changed dramatically in September of 2013, when USDA's National Organic Program announced a major shift in this policy, without undertaking a full notice and comment process.

I am hearing a lot of concern from the organic community about both the process and substance of this policy change for such a critical and unique aspect of the USDA organic program, which is tied to the integrity of the organic label.

Until USDA's policy change, the same high hurdle of scientific scrutiny used to consider a material's usage in organic when it was first allowed was also used to review it after 5 years. The policy required a 2/3rds vote of the NOSB for the initial placement of a material on the "National List" to allow its usage in organic, and also required a 2/3rd vote of the NOSB after 5 years to allow the material to be renewed and remain on the List for another 5 years. Now, under the new policy, once a material is on the List, it stays on the List unless 2/3rds of the Board members vote to remove it from the List of allowed materials. This is a reversal of the previous policy and procedure.

Can you explain why USDA would make such a big policy change in this process, and reinterpretation of the law, without any notice and comment process?

*Answer.* USDA strongly supports organic agriculture, and is committed to establishing a level playing field that protects all organic farms and businesses. Public participation is vital to USDA's work in organics, and we always encourage all members of the public to take part in opportunities to do so.

On September 16, 2013, the National Organic Program announced a revised sunset review and renewal process that would help protect organic farmers and consumers. We also increased public engagement and transparency, allowing more opportunity for public comment by providing two public comment periods for each substance undergoing sunset review.

This matter is currently under pending litigation and we are not able to comment further.

#### FOREST MANAGEMENT

*Question.* In the budget request, the Forest Service talked a lot about ecological resiliency. This is important to Wisconsin stakeholders, given that their livelihoods and way of life depends on a healthy forest. But economic resiliency is also fundamentally important in Wisconsin. In contrast to other states, in Wisconsin we are fortunate to have a forest products industry that can partner with the Forest Service to accomplish Federal goals for timber management, forest restoration, ecosystem services, and infrastructure repair.

The Forest Service is not doing enough to address the economic resiliency of our communities which are dependent on the forest. Our industry partners, and many conservation partners, are frustrated with the agency. They would like to see more transparent communication from the forest and region about timber sale goals. They would like to dialog with the agency about the content and timing of upcoming sales, so that industry can plan other work on non-Federal land, and ensure our

hardwood and pulpwood mills have a steady supply of material. They would like to see more work done.

What tools in the budget are most important to accelerating active forest management in Wisconsin? What tools does the agency need to achieve this goal?

*Answer.* Forest Products, Vegetation Management, and Roads budget line items are critical in supporting all activities for the timber program and to increase the pace and scale of restoration. Resources to support the road system, including replacement/repair of bridges, are critical to achieving the forest management goals. These budget line items have been negatively impacted by increased fire suppression costs over the years. The primary tool that the agency needs to address accelerated forest management in Wisconsin, as elsewhere, is the fire cap adjustment. Funding extraordinary fires outside the agency cap will free up resource dollars under the Interior bill's currently tight discretionary funding caps. This will help fund key restoration, fire preparedness, and infrastructure programs, including Integrated Resource Restoration, CFLRP, Suppression, Landscape Scale Restoration, and it allows high levels of investment in Hazardous Fuels to be maintained from prior years. These restoration programs help create healthier, more resilient, and more fire-adapted landscapes where fire can visit a site with less than devastating consequences and communities are better able to live with fire and other disturbances.

#### SUBCOMMITTEE RECESS

Senator MORAN. I thank everyone again for attending today's hearing, and we are adjourned.

[Whereupon, at 11:11 a.m., Tuesday, March 17, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

**AGRICULTURE, RURAL DEVELOPMENT, FOOD  
AND DRUG ADMINISTRATION AND RELATED  
AGENCIES APPROPRIATIONS FOR FISCAL  
YEAR 2016**

---

**WEDNESDAY, SEPTEMBER 16, 2015**

U.S. SENATE,  
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,  
*Washington, DC.*

The subcommittee met at 2:06 p.m. in room SD-192, Dirksen  
Senate Office Building, Hon. Jerry Moran (chairman) presiding.  
Present: Senators Moran, Daines, Merkley, and Feinstein.

**FDA FOOD SUPPLY SAFETY EFFORTS**

**STATEMENT OF HON. DR. STEPHEN OSTROFF, ACTING COMMIS-  
SIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF  
HEALTH AND HUMAN SERVICES**

**ACCOMPANIED BY:**

**MICHAEL TAYLOR, DEPUTY COMMISSIONER FOR FOODS AND  
VETERINARY MEDICINE; FOOD AND DRUG ADMINISTRATION  
WILLIAM TOOTLE, DIRECTOR, OFFICE OF BUDGET, FOOD AND  
DRUG ADMIN**

**OPENING STATEMENT OF SENATOR JERRY MORAN**

Senator MORAN. Good afternoon to the witnesses, as well as  
those in the audience. This hearing will come to order.

Today's hearing will focus on the Food and Drug Administra-  
tion's (FDA's) effort to improve and maintain safety of our food sup-  
ply. And I thank you, Commissioner Ostroff, for your presence here  
today, Mr. Taylor and Mr. Tootle for participating in this hearing.  
We are delighted for that. And, Dr. Ostroff, I appreciate the warm  
working relationship that we are developing, and I appreciate the  
conversations and dialogue that we have had on a number of FDA  
issues over the last several months. So thank you personally and  
professionally for the way that you are treating me as the new  
chairman of this subcommittee.

**FSMA**

You note in your testimony, Commissioner, that nearly one in six  
Americans fall victim to foodborne illness each year. Americans ex-  
pect that the food they purchase at a grocery store or restaurant  
will be safe. And the FDA is largely tasked with maintaining that  
confidence. Passage of the Food Safety Modernization Act (FSMA)  
in 2010 gave your agency significant new responsibilities in imple-

menting a very sweeping set of changes to the food safety laws, certainly the largest change in the last 70 years. Our hearing today is timely as it follows last week's publishing of the first two final rules for preventive controls on human and animal foods.

In delivering these new regulatory responsibilities, your private sector partners expect transparency and certainty from the FDA. And when I speak to small businesses and agricultural producers in my home State, their major concern is a Government that limits job creation and stifles innovation through burdensome regulations. I am pleased that the agency took many of the suggestions and comments from the agricultural community into account by re-proposing portions of the FSMA rules because they were unworkable for farmers. And I thank you for that.

Modernizing the FDA's regulatory controls and educating industry and consumers are at the heart of FSMA implementation, and the issuance of the preventive control rules starts the compliance process. It is vital that FDA continue its collaboration with the industry and other Federal and State agencies and issue proper regulatory guidance throughout this process.

#### FSMA FUNDING

I also recognize that successful implementation—this is the part that you want me to say, Mr. Commissioner. I also recognize that successful implementation does not come without a cost. And this subcommittee remains committed to investing in FSMA's implementation within the resources that are at our disposal and has done so since FSMA's enactment in 2011. I think spending in the last 5 years has increased 8 percent, something that cannot be said for many other Federal agencies. But we know that you face additional challenges and additional tasks, and we are interested in exploring how we can be more helpful. And as the process continues for appropriations this year, FSMA funding will undoubtedly play a significant role in our deliberations and in establishing priorities.

#### PREPARED STATEMENT

I look forward to discussing FSMA and other food safety topics with our witnesses today.

[The statement follows:]

#### PREPARED STATEMENT OF SENATOR JERRY MORAN

This hearing will come to order. Good morning. Today's hearing will focus on Rural Development at the Department of Agriculture and its strategic investments in rural America. Thank you Under Secretary Mensah, Administrator Hernandez, Administrator Ridders, and Administrator McBride for being here today. Under Secretary Mensah, I enjoyed visiting with you recently in Kansas and hope you will return soon and often.

Agriculture remains one of the bright spots in our nation's economy, supporting more than 16 million jobs nationwide and forming the backbone of our rural communities. For those of us who grew up in rural areas, it is a lifestyle we cherish and hope to preserve for our children and future generations to come. Rural Development is largely tasked with maintaining and improving that quality of life. Whether it's providing loans for low-income families to own their first home, spurring economic development with grants to small businesses, or providing communities with financing to allow customers affordable utility rates, Rural Development continues to serve a significant role in the nexus between need and opportunity.

In my home state of Kansas, we determine economic development by whether or not your town has a grocery store. Many issues facing rural communities are unique

to those areas in an ever-increasing urbanized and technologically-advanced world. I look forward to discussing the Rural Development mission and other relevant topics with our witnesses today. We have a lot to cover this morning, so I will turn it over to Senator Merkley for any remarks he may wish to give.

Senator MORAN. We have a lot to cover this afternoon, and I turn now to my colleague, Senator Merkley, for any remarks that he may wish to give.

#### STATEMENT OF SENATOR JEFF MERKLEY

Senator MERKLEY. Thank you very much, Mr. Chairman and thank you for holding this hearing.

I thank you, Dr. Ostroff, Mr. Taylor, Mr. Tootle, for attending.

#### FOOD SAFETY

The safety of our food supply is something that most Americans take for granted. For parents that enter the grocery store, for the most part, they do not have to give a second thought to whether or not the food that they are picking up for their family will make their family sick. America has and continues to have the safest food supply in the world.

But that, of course, does not mean that it is perfect, as anyone who has ever had a foodborne illness will testify to. And we need to continually work to make sure we stay ahead of a changing global marketplace. We do not think anything about eating strawberries or melons out of season because we have access to food from all over the globe. To stay ahead of this is a monumental task, and there are multiple Federal agencies involved, including the U.S. Department of Agriculture (USDA) which regulates about 20 percent of our food supply, and FDA which regulates 80 percent. Outside of the Federal Government, State agencies, private businesses, and farmers are working continually to make sure that the processes and procedures in place will make sure a domestic onion is always safe to eat, as well as an imported strawberry.

The Food Safety Modernization Act, which was signed into law in 2011, was the most sweeping update of our food safety laws in nearly 70 years. The law changed the way we look at the issue of food safety. Prior to FSMA, an outbreak would take place, and we would spend our time and resources tracking it down. Now we are working to make sure that we prevent that outbreak from occurring in the first place and giving FDA the tools and the teeth it needs to do just that. It is a better way to do business.

The law had about 50 specific deliverables, no small task for any agency. And although it took longer than many would like, FDA published two of the seven major final rules last week, and the rest will be out, as I understand, by next spring. We are at the point where the rubber meets the road, and it is going to require a new way of thinking for food inspectors who have been trained to look for an existing problem instead of working with industry to make sure those problems never materialize in the first place.

It is not always smooth sailing, and I know the folks at FDA have learned a lot about production agriculture and food processing along the way. I think most people would agree that you have done a good job working with industry to make sure that these new rules are effective while minimizing the disruption.

So, again, thank you, Mr. Chairman, for holding this hearing. It is timely and I am very interested to hear from our witnesses.

Senator MORAN. Dr. Ostroff, again, welcome and you may commence your testimony. It is a significant number of pages, and I have extended the deadline from the normal 5 minutes to 10. So please proceed.

#### SUMMARY STATEMENT OF DR. STEPHEN OSTROFF

Dr. OSTROFF. Thank you, Senator Moran and other members of the committee.

And I share your enthusiasm for the very warm working relationship that we have been able to develop in the last several months, and we look forward to continuing to work with you not only on food safety issues but all the other issues that FDA deals with.

So I am Steve Ostroff, the acting Commissioner of Food and Drugs, and I really very deeply appreciate the opportunity for Mike Taylor, who is sitting to my left, and me to be here to talk about the Food Safety Modernization Act, also known as FSMA.

I would also like to thank you for holding this hearing and for the committee members and their ongoing interest in this particular topic and for the strong and growing working relationship that has developed between the committee and the FDA to achieve our mutual goals of assuring the safest food supply in the world for American consumers.

#### FOOD SAFETY

I hope that everybody in this room knows that this is Food Safety Month, and I cannot think of a better way to celebrate than by starting the process of bringing FSMA's important new rules online as we did last week and by discussing with you today the critical next steps that must be taken to realize the goals of FSMA.

So although I have only been working at FDA for 2 years, I actually began my public health career considerably before that 30 years ago when I was working at the CDC on food safety and foodborne diseases, particularly at that time the newly recognized and deadly pathogen, E. coli O157. While working in Washington State close to Oregon, over a 2-year period, I personally interviewed every person or a member of their family in the State diagnosed with that particular infection and visited a number of them in their homes. I subsequently did the same with people with other illnesses from foodborne pathogens. So I can say, without question, that I have a very deep appreciation for the suffering and consequences of foodborne illness and have carried that perspective throughout my career as a public health practitioner and as a physician. In fact, food safety was the reason that I joined FDA in 2013 at the urging of the person sitting to my left.

Despite today having much improved technical methods to detect and investigate foodborne illness from when I started my career 30 years ago, along with some notable successes in reducing the incidence of certain pathogens, there simply remains too much foodborne illness. As you mentioned, nearly one in six Americans fall victim to foodborne illness each year. That is 48 million people. Of these, 128,000 are hospitalized and 3,000 die. This burden of

foodborne illness is shared by each and every one of us, consumers and food producers alike. The economic costs are also quite sizable. Since we know that the illnesses, hospitalizations, and deaths can be prevented, we must also, quite frankly, acknowledge that it is simply time to start preventing them.

So over here on this side, the Centers for Disease Control and Prevention's (CDC's) FoodNet data has shown that for many, many years now, the burden of illness due to the major foodborne pathogens remains essentially unchanged. As you can see, the illness burden from some pathogens goes up while for others it goes down. But looking at the poster over here on the other side of the room, in total the line remains distressingly flat. So I say to you that it is time to make that line start bending in the right direction. We believe that we now have the tool to be able to do that, and that tool is called the Food Safety Modernization Act.

#### FSMA

During my time at FDA, I have been thrilled to be able to participate in the process of modernizing our food safety system. This agency has stepped up to solve problems by identifying the best science and risk-based solutions that can benefit both consumers and industry. That is what we do at FDA when we are confronted by such problems. I know that Mike and his team have embedded this concept in their work to modernize the Nation's food safety system through FSMA so that it can meet the challenges of a new global era.

The enactment of FSMA was unquestionably the product of foresight and the recognition of common interests. Members of Congress on both sides of the aisle came together with consumers and with food industry leaders to enhance this ability to protect the food supply in a modern, diverse world of free-flowing commerce. FSMA stands for the proposition that the standard across the food system should be to have processes in place that we have learned work to prevent food safety problems, practices that many food safety producers are already implementing. This means having prevention-oriented standards in place that are equally applied to domestic and foreign producers, reasonable verification of compliance with those standards, and accountability for those who are unable or unwilling to comply. FSMA directs FDA to build a modern food safety system based on these central ideas.

FDA has fully embraced a dynamic, collaborative approach to implementing FSMA and is working very hard to build the new partnerships and to strengthen existing ones. This effort includes the food industry, from farmers and manufacturers to transporters and importers whose capacity and responsibility under FSMA for producing safe food is the absolute foundation of the new system. It also includes the FDA's food safety partners in other government agencies at the Federal, State, tribal, and local levels, and it also includes foreign governments, which can play an important role to help assure that the foreign supplies to the U.S. market are being produced in safe fashion. And it includes consumers and patient advocates who have been victims of foodborne illness because after all, ultimately, they are the ones that we are doing this for.

## PREVENTIVE CONTROL RULES

The two final preventive control rules we issued last week are critical linchpins for building our new food safety system. They focus on implementing modern food manufacturing processes for both human and animal foods, thus ensuring the food companies are taking a 24/7 365-day a year approach and working with the FDA to prevent problems on the front end rather than waiting until a problem is recognized through identifying people with foodborne illness as you know happened in your State of Kansas earlier this year.

These rules are important in their own right, but they are only the first in a number of steps towards building a comprehensive food safety system. Three more rules will be finalized by the end of this year, those being the produce rule, foreign supplier verification process, and accredited third-party certification. Then the final tools will be issued this spring, sanitary transport and intentional adulteration. Together, these rules form the integrated holistic network for food safety called for by FSMA, all based on the principle of prevention.

Writing the rules is clearly a big step, but it is only the first step. Right now, they exist on paper. The bigger challenge ahead is implementing those rules and making them exist on the ground. We strongly believe that if we do not implement the new FSMA-mandated food safety system in the comprehensive way that Congress envisioned right from the start, that we will fail to achieve the FSMA goals of food safety, strengthen consumer confidence and a level playing field for U.S. producers. The line mentioned earlier will not bend as it should and it must go.

## PREPARED STATEMENT

So I am very proud of this work and I am proud of our team. Mike Taylor alone has been a force of nature when it comes to FSMA. So please continue to work with us to achieve the level of funding that we need to accomplish on the ground what is set in statute and in rule. American consumers are depending on us and they expect this of us.

So I will just end by thanking you again for your support of FDA and for the opportunity to be here to discuss FSMA with you.

[The statement follows:]

## PREPARED STATEMENT OF DR. STEPHEN OSTROFF

## INTRODUCTION

Good morning, Chairman Moran and Members of the Subcommittee, I am Dr. Stephen Ostroff, Acting Commissioner of Food and Drugs. I am accompanied today by Michael Taylor, FDA's Deputy Commissioner for Foods and Veterinary Medicine. Thank you for the opportunity to appear before you today to discuss the Food and Drug Administration's (FDA) implementation of the FDA Food Safety Modernization Act (FSMA) and our role in ensuring food safety. I would like to thank the Subcommittee for its past investments in FDA, which have helped us meet the demands of our broad and increasingly complex mission.

I would also like to acknowledge that it was Congress' vision of a safer America that fueled the enactment of FSMA in 2011. You shared, and responded to, a widespread concern among consumers, industry, and your fellow legislators about the deadly foodborne illnesses that endanger the public health.

## TODAY'S FOOD SAFETY CHALLENGE AND FDA'S CHANGING ROLE UNDER FSMA

FDA is a science-based public health regulatory Agency with mandates from Congress that span the human and animal food supply, human and animal drugs, medical devices, vaccines and other biological products, cosmetics and tobacco—products that all have profound implications for the health of consumers and the nation's economy. Like other areas of FDA's responsibility, our mandate to ensure the safety of the nation's food supply is of fundamental importance to the welfare of consumers and the industries we regulate.

FDA's responsibility for food safety dates back to 1906, when Congress first established prohibitions on the sale of adulterated food and gave FDA authority to enforce those prohibitions. FDA has used those authorities, which were largely unchanged until Congress passed FSMA, to conduct inspections and take enforcement action in response to specific cases of insanitation in food facilities, dangerous contamination of food products, and outbreaks of foodborne illness. Through these efforts and the commitment of the great majority of food producers who want to produce safe food, we have long had one of the safest food supplies in the world. And with the implementation of FSMA, our food supply will become safer.

According to estimates by the Centers for Disease Control and Prevention (CDC), every year nearly one in six Americans falls victim to foodborne illness. That's 48 million people. Of these, 128,000 are hospitalized, and 3,000 die. This burden of foodborne illness is damaging to consumers and food producers alike. And the tragedy underlying the numbers is magnified by the fact that most of these illnesses and deaths are preventable.

In the years leading up to the enactment of FSMA, a series of major illness outbreaks, contamination incidents, and product recalls—involving both domestic and imported food—focused the food industry and government on how the food safety system could work more effectively to prevent food safety problems, rather than relying so much on response after the fact. The food industry developed best practices, involving such measures as the implementation of preventive controls in food facilities, and government took incremental steps to require such controls for FDA-regulated seafood and juice processors and in meat and poultry facilities regulated by the U.S. Department of Agriculture (USDA).

Other than those incremental changes affecting a few food categories, FDA's reactive approach to food safety had changed little over the years, despite radical change in the food system. Compared to 1906, we now have a vast, complex and global food system in which changing technology, changing consumer preferences and behavior, and supply chains that extend around the world make food safety a bigger challenge than ever before. We also have seen rapid expansion in the local food movement, with many small-scale growers and processors coming into the market in response to consumer demand for locally and sustainably grown food.

All of this change and diversity in the food system is good for consumers, and creates great opportunity for American business. But it also places added pressure on our food safety system because consumers and industry alike agree: we all want food to be as safe as we can make it, and we all want to have confidence in the safety of our food, whether it comes from around the corner or from the other side of the world.

That alignment of interests is what led to the enactment of FSMA. FSMA stands for the proposition that what we have learned works to prevent food safety problems—practices that many food producers are already implementing—should be the norm across the food system. This means having prevention-oriented standards that apply equally to domestic and foreign producers, reasonable verification of compliance with those standards, and accountability for those who are unable or unwilling to comply.

FSMA directs FDA to build a modern food safety system based on these central ideas. As outlined below, this has involved developing new regulations requiring modern preventive controls in facilities producing all types of food commodities, not just a few, and establishing requirements where they haven't existed before, most notably for produce growers, food importers, and food transporters.

FSMA also directs FDA to do its food safety work in new ways, with a heavy emphasis on collaboration and partnership. This collaboration includes the food industry—from farmers and manufacturers to transporters and importers—whose capacity and responsibility under FSMA for producing safe food is the foundation of the new system. It also includes FDA's food safety partners in other government agencies at the Federal, state, tribal, and local levels, with which Congress directed FDA to build upon our history of collaboration to ensure effective and efficient implementation of FSMA. And it includes foreign governments, which can play an important role in helping to ensure that foreign suppliers to the U.S. market are producing

safe food. FDA strongly embraces this collaborative approach and is working hard to build new partnerships and strengthen existing ones.

FDA recognizes, however, that part of the change that has to happen for FSMA to succeed must happen within FDA and in how FDA conducts its food safety oversight program. To that end, and as discussed below, FDA has developed a strategy for implementing the new FSMA rules that is a fundamental departure from the past.

We believe that we will achieve high rates of compliance more quickly and efficiently by tapping into the fact that the great majority of firms we regulate want to produce safe food and want to comply. That's why our strategy takes an "educate before and while we regulate" approach, especially in the produce area, so that, through FDA guidance, outreach, and technical assistance, we can help food producers understand and accomplish what is required. It entails an approach to inspection that is aimed first at fostering and facilitating compliance, rather than at finding and penalizing regulatory violations. We will of course take swift regulatory action when needed to protect consumers when we find dangerous practices, but our focus is on prevention.

FDA is firmly committed to implementing FSMA the right way from the start. This means investing in the food safety culture change that is happening within FDA, but it also means being faithful to the comprehensive, holistic vision of food safety modernization laid out in FSMA. Congress directed FDA to build a modern food safety system, addressing food safety challenges across the spectrum of farms, manufacturers, and transporters of food, both domestic and foreign. The pieces of this system are closely interconnected. We cannot credibly hold domestic producers to the new standards if we are not doing the same for importers and their foreign suppliers. Nor can we do the reverse, holding importers and foreign suppliers, but not domestic producers, to new requirements. We believe that if we do not have the resources necessary to implement the new FSMA-mandated food safety system in the comprehensive way Congress envisioned, from the start, we will fail to achieve the FSMA goals of food safety, strengthened consumer confidence, and a level playing field for U.S. producers.

In the remainder of this testimony, I will outline our achievements to date in developing the FSMA rules and planning for their implementation, and I will explain why the President's fiscal year 2016 budget request is so essential to the success of FSMA.

#### SEVEN FOUNDATIONAL FSMA RULEMAKINGS

As a first major step toward making the promise of FSMA a reality, FDA has proposed seven foundational rules, starting in January 2013. Together, they will provide a modern food safety foundation that brings to bear the most recent science, that is risk-based and focuses effort where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. We have designed the rules to be both effective for food safety and workable across the great diversity of our food system.

Last week, FDA issued the first two of the final rules listed below and is on target for finalizing the remaining five in the coming months.

1. **Preventive Controls for Human Food.** This rule will improve the safety of manufacturing, processing, packing, and holding human food in two key ways. First, it modernizes FDA's longstanding Current Good Manufacturing Practice (CGMP) regulations. Second, it requires facilities to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, and specify actions to correct problems that arise. The rule is designed to be flexible, practical, public health protective, and consistent with industry best practices.

2. **Preventive Controls for Animal Food.** This rule will improve the safety of animal food, including pet food, livestock food, and raw materials and ingredients used in food for animals, by establishing general CGMPs for the first time, tailored to animal food, and establishing the same, flexible requirements for risk-based hazard analysis and preventive controls as the Preventive Controls for Human Food rule.

3. **Produce Safety Standards.** This rule will improve the safety of produce—fruits and vegetables that are typically consumed raw—by establishing science-based standards for growing, harvesting, packing, and holding produce on farms. The rule addresses identified routes of microbial contamination, including agricultural water, biological soil amendments of animal origin, health and hygiene of farm personnel, animals in the growing area, and equipment, tools, and buildings.

4. **Foreign Supplier Verification Programs.** This rule will strengthen the oversight of foods imported for U.S. consumers by requiring importers to perform risk-based activities to verify that food imported into the United States has been produced in

a manner that provides the same level of public health protection as that required of domestic food producers. This rule is the foundation for the multi-faceted new import safety system that Congress mandated to protect food safety, strengthen consumer confidence, and maintain a level playing field for U.S. food producers.

5. Accredited Third Party Certification. This rule will improve the safety of imported food and allow more efficient use of FDA resources by providing an opportunity for foreign food producers to voluntarily become certified by third-party certification bodies accredited under FDA's oversight. FDA may in turn use that certification to determine whether an importer is eligible to participate in FSMA's voluntary qualified importer program, or whether to admit certain imported food into the United States that FDA has determined poses a food safety risk. Both accreditation bodies and auditors must meet standards for legal authority, competency and capacity, impartiality/objectivity, quality assurance, and records procedures.

6. Sanitary Transportation. This rule will help ensure the safety of human and animal food during transportation by establishing requirements for shippers, carriers, and receivers of food in the U.S. Those requirements include ensuring that the design and maintenance of vehicles and equipment does not leave foods vulnerable to contamination, and taking measures during transportation to ensure that food is not handled improperly or contaminated, including using adequate temperature controls and separating food from non-food items in the same load.

7. Intentional Adulteration. This rule will help to ensure the safety and security of the food supply by requiring facilities to address vulnerable processes in their operations in order to prevent acts on food intended to cause large-scale public harm (e.g., acts of terrorism).

#### FDA'S COMMITMENT TO STAKEHOLDER ENGAGEMENT

Throughout the rulemaking process, outreach and stakeholder engagement have been central to developing rules that are both practical and protect the public health. FDA has worked intensively with industry stakeholders, consumers, and regulatory partners to be sure we get the rules right and to set the stage for successful implementation of the rules once they are final.

Since FSMA was enacted in 2011, FDA has been involved in approximately 600 engagements with stakeholders on FSMA and the proposed rules, including public meetings, webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups. Even before publishing the proposed rules, FDA held public meetings to gather input on the rules' content. Since the release of the proposed rules beginning in early 2013, we have continued our commitment to outreach, engaging various industry, consumer, and other interested groups across the country and internationally.

We have heard the concerns raised by stakeholders and have adjusted the rules to include solutions to those concerns. As part of this stakeholder dialogue, FDA took the unusual step of issuing four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on revised language. Again, after the supplemental notices were issued, we engaged stakeholders to make sure our final rules would be where they needed to be. As a result of this extensive public engagement, along with our consideration of tens of thousands of formal written comments submitted to the public dockets on the rules, we are confident the rules that have been finalized and the five remaining final rules in development are flexible, practical, and consistent with industry best practices, while also being public health protective and consistent with our statutory mandate.

As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders through guidance, education, training, and technical assistance, to ensure that everyone understands and successfully plays their role in food safety. FDA believes that these seven foundational final rules, when implemented, will fulfill the paradigm shift toward prevention that was envisioned in FSMA and will be a major step forward for food safety that will protect consumers into the future.

#### ENSURING SUCCESSFUL FSMA IMPLEMENTATION

The success of building a modernized food safety system depends on FDA and industry working together, as well as working with State and other regulatory and public health partners, after the final FSMA rules are issued. In May 2014, FDA released a FSMA Operational Strategy Document (attached as an appendix to this testimony) that focuses on how FDA intends to implement FSMA, by prioritizing prevention, voluntary compliance, risk-based oversight, and expanded collaboration across the food safety community. Effective FSMA implementation will require a sea

change in how FDA, as an agency, approaches regulatory oversight of the food industry.

Inspection and compliance will be specialized, strategic, and risk-based. FDA is reshaping itself to oversee industry compliance in a manner that is strategic and based on risk. We are developing a new inspection paradigm focused on whether firms are implementing systems that effectively prevent food contamination, requiring fundamentally different approaches to food safety inspection and compliance. To effectively leverage our resources, we will use more targeted, risk-based inspection models to screen firms for food safety performance and to guide inspection priority, frequency, depth, and approach. Inspections will be systems-based, with noncompliance viewed in the context of the performance of the firm's overall food safety system and the risk to public health. In addition, FDA's inspection and compliance staffs will be trained to be specialists in food oversight, rather than covering the broad spectrum of FDA-regulated products. Members of these staffs will be teamed with FDA subject matter experts to facilitate the timely correction of problems and consistent, informed enforcement of the new FSMA regulations. Finally, FDA intends to continuously improve its inspection strategy through targeted data collection, timely analysis, and regular program evaluation.

FDA will educate before and while we regulate. Stakeholder engagement has been a cornerstone of the FSMA rulemaking process, and FDA will continue to work closely with industry and other stakeholders to achieve widespread compliance with the rules through education and technical assistance. We are currently drafting general guidance on each rule, guidance for small entities, guidance for specific commodities and sectors, and guidance on key provisions, to help industry understand their new regulatory obligations under FSMA. We are also developing a comprehensive training strategy to give food producers, focusing on small and mid-size operators, the tools they need to meet the FSMA requirements that apply to them.

For example, FDA created three alliances, or public-private partnerships, to develop training materials and create an education and technical assistance network. The Food Safety Preventive Controls Alliance and the Sprouts Safety Alliance are being coordinated by the Illinois Institute of Technology, and the Produce Safety Alliance is being coordinated by Cornell University. All three alliances bring together FDA, local and state food protection agencies, the food industry, and academia to determine what will work best to help prepare food facilities and farms to implement FSMA.

FDA has also joined with USDA's National Institute of Food and Agriculture to manage a competitive grant program that will provide food safety training, education, extension, outreach, and technical assistance to farm owners and operator, small food processors, and small fruit and vegetable merchant wholesalers. FDA plans to fund additional training programs through cooperative agreements.

Finally, FDA is building a technical assistance network to provide rapid support to food producers, providing answers to any questions they have about how to comply with the new regulations.

FDA will work closely with governmental and other stakeholder partners. A key element of our stakeholder outreach during the development of the FSMA rules has been outreach to our regulatory partners. As we transition to implementation, our partnerships with Federal, state, tribal, territorial, local, and international regulatory and public health agencies will be even more vital. We are continuing to build a National Integrated Food Safety System to ensure the quality, consistency, and effectiveness of local, state, and Federal efforts to protect the food supply. In addition, FDA will be relying heavily on state agriculture and health departments and other state and tribal agencies with food safety responsibilities, especially for the new and unique challenges of implementing the forthcoming produce safety rule on farms. We recognize the importance of harnessing the food safety commitment, knowledge of local conditions and practices, and local presence of these other regulatory entities to provide training, technical assistance, and compliance oversight in an effective manner.

Successful FSMA implementation is dependent on FDA's continued engagement with states, industry, consumer groups, and foreign partners throughout the process, to ensure that we continue to do our job in a practical, effective, and risk-based way.

#### HOW FSMA WILL MAKE A DIFFERENCE

The prevention model for food safety adopted by Congress in FSMA is widely recognized in the food industry and among government and academic food safety experts as the optimal approach to minimizing food safety hazards and managing problems when they do occur. FSMA also transforms FDA's oversight by focusing

us on prevention and giving us new tools to verify and ensure that prevention is happening. Two recent incidents from just this year illustrate why we need the preventive system envisioned by FSMA.

*Preventive Controls in Food Facilities: Blue Bell Creamery*

This case involved the presence of the unusually dangerous bacterium *Listeria monocytogenes* (Lm) in the manufacturing plants of an ice cream company. The resulting contamination of products was associated with the deaths of three people in Kansas and caused numerous illnesses in at least three other states. Under current industry best practices, manufacturers of ready-to-eat products like ice cream should have a sanitation plan and standard operating procedures that are adequate to ensure that Lm does not become entrenched in the facility, and they should conduct sampling and testing under an appropriate environmental monitoring program to verify that the presence of Lm and the potential for product contamination have been minimized.

Under the pre-FSMA food safety system, however, no such plans, procedures or monitoring were specifically required. The burden rested on FDA to find the problem, through inspection or, as in this case, via reports of product contamination and illness. Moreover, during pre-FSMA inspections, FDA could not require access to the company's production and food safety records to look for evidence of problems or for documentation that the firm was doing its food safety job appropriately. FDA could only observe what the company was doing on the days of the inspection. FDA was basically in a reactive mode, with the burden on FDA to find problems, often investigating problems after the harm was done, and being limited largely to finding evidence of legal violations suitable for taking cumbersome and time consuming court enforcement action.

Under FSMA and the preventive control rules FDA issued last week, we now have requirements for sanitation controls, environmental monitoring, and corrective actions that will apply to facilities making ready-to-eat foods such as ice cream. The preventive controls rules define the framework within which companies must put in place a food safety program that is appropriate for the hazards in their products and facilities. Companies will now be legally accountable to FDA for doing the right thing to minimize hazards like Lm, and FDA will be able not only to inspect the operations and conditions in the facility, but also to examine, on an ongoing basis, the company's records documenting the design and proper implementation of its food safety plan. With these new requirements, enhanced records access, and FSMA's administrative enforcement tools, there will be real accountability for prevention in food manufacturing facilities.

*Produce Safety and Imports: Cilantro from Mexico*

Mexico is a major source of a wide range of produce commodities, from staple fruits and vegetables to peppers and herbs, on which Americans depend for year-round access. FDA and our Mexican counterparts have long recognized the challenge of adequately ensuring and verifying the safety of produce in general, and the large volume of produce crossing the U.S.-Mexico border, a challenge exemplified by a series of outbreaks of illness in 2012, 2013, 2014 and 2015 caused by the parasite *Cyclospora* associated with fresh cilantro from the Puebla region of Mexico. This year's outbreak has resulted in approximately 500 confirmed cases of illness in 30 states. Like most produce safety problems, we have learned that the risk of contamination can be reduced by following recognized practices related to water quality, employee hygiene, biological soil amendments, animals in growing areas, and harvesting and packing of produce.

Before FSMA, there were no regulatory standards for such preventive practices, only voluntary guidelines. Moreover, to oversee the safety of imported produce, prior to FSMA FDA has had to rely on computer screening and on inspectors at the border physically checking a small percentage of import shipments, looking for problems. If FDA can find the problem, it can keep the problem out, but this reactive approach is widely recognized to be inadequate for the huge volume of produce and other commodities flowing into the United States from scores of countries. In the case of cilantro from Mexico, the contamination has to be prevented at its source.

Under FSMA, we will soon have prevention-oriented produce safety requirements that apply to both domestic and imported produce, including cilantro. Moreover, the Foreign Supplier Verification Programs (FSVP) requirement under FSMA will, for the first time, make importers an accountable part of the food safety system. Instead of relying primarily on FDA and its inspectors to detect and correct problems at the border, we will also be able to hold importers, and in turn their foreign suppliers, accountable for preventing the problems. This will make a big difference for food safety.

Recognizing the challenge of produce safety and the importance of FSMA's success, in 2014 we launched with our Mexican regulatory counterparts a Produce Safety Partnership. This partnership is grounded in our common interest in ensuring the safety of Mexican produce, our shared commitment to FSMA's prevention strategy, and the directive in FSMA for FDA to collaborate on food safety with foreign governments. The partnership with Mexico includes collaboration with the U.S. and Mexican produce industry so that we can coordinate with and take advantage of industry's own efforts to improve the safety of imported produce.

Such partnerships are resource intensive for FDA, but can pay big dividends when, as in the case of Mexico, we can leverage the efforts of regulatory partners who are also real food safety partners. In the current cilantro case, we are implementing jointly with Mexican authorities a program that includes continued FDA oversight at the border, but that also requires future shipments entering the U.S. from Puebla to come only from farms that have been inspected and certified by the Mexican authorities to be operating in accordance with sound food safety practices.

#### FDA'S FISCAL YEAR 2016 PRESIDENT'S BUDGET REQUEST FOR FOOD SAFETY

The fiscal year 2016 President's Budget includes a \$109.5 million increase in budget authority, a total of \$1.3 billion, for FSMA implementation, and a total of \$1.5 billion when accounting for all resources requested in fiscal year 2016. Full funding of the President's budget authority request is essential to maintaining momentum toward the timely implementation of FSMA in the most effective way possible. This goal could be undermined if FDA, the states and the industry are not adequately prepared to get implementation right. The three major program areas where successful implementation hinges crucially on the fiscal year 2016 budget authority request are preventive controls in food facilities, produce safety, and imports.

For preventive controls, the essential investments are for inspector training and modernization of the inspection process, as conducted both by FDA and the states, and essential guidance and technical assistance for industry so firms can know what is expected and can be supported in complying with the new requirements. This is especially crucial for small and mid-size firms. These investments are time sensitive because the preventive controls rules are the first to go into effect, and FDA is mandated by FSMA to conduct inspections in the covered food facilities at a certain frequency. If these investments are not made, industry could experience inconsistency, inefficiency, and potential disruption stemming from FDA staff who are not adequately prepared for the new system.

Produce safety is one of our most important public health priorities: we want people to consume more fresh produce, yet we continue to experience an unacceptable number of illness outbreaks from both domestic and imported produce. The top domestic produce safety investment priority in fiscal year 2016 is for states to have the capacity to be FDA's on-the-ground partner in implementing the FSMA produce safety rule that will be issued later this fall. As Congress envisioned in FSMA, our implementation strategy for produce is based on the states playing a key role in working with growers to provide education and technical assistance, and they will also be the primary provider of inspections to verify compliance. In support of this strategy, FDA and the National Association of State Departments of Agriculture (NASDA) have entered into a five-year cooperative agreement through which we are jointly planning implementation of the produce safety rule from the ground up.

The states' role is essential to success, but they cannot perform the role without resources. Investment is essential in 2016. We will have a produce safety rule on the books by this November, but, because this is a new area of regulation, we are having to build an implementation system from the ground up. Growers, especially small and mid-size operators, are already seeking education, training and technical assistance, which states simply lack the capacity to provide. States also need resources now to build the capacity they will need to carry out meaningful on-farm compliance assessments and inspections in 2016 and 2017.

Finally, for imports, FDA must have new resources to adequately implement FSMA's groundbreaking new FSVP requirement. There is no more essential element of FSMA and its successful implementation than this. FSVP is the crucial tool that FSMA provides FDA to hold importers accountable for the safety of the food they bring into the United States. They must meet this responsibility by verifying the adequacy of the food safety controls being implemented by their foreign suppliers, which means that FSVP is also the primary means of holding foreign suppliers to the same food safety standards as domestic producers, as FSMA intends. For the FSVP requirement to fulfill its purpose, FDA must have funding in fiscal year 2016 to retrain existing staff, to hire new staff with the skills needed to evaluate complex

global supply chain management systems, and to deliver education, training and technical assistance to the importers we estimate are subject to the FSVP rule.

This funding will also provide the foundation for building the multi-faceted new import safety system called for by FSMA, including more foreign inspections by FDA, expanded collaboration with foreign food safety authorities, and capacity building in countries where that will help protect food safety in the U.S. Receiving this funding is essential in fiscal year 2016 in order to align implementation of FSVP with the preventive controls and produce safety rules.

In sum, FSMA directs FDA to build a comprehensive new food safety system, based on what we know works to prevent problems—a system that is effective regardless of where food comes from. In order for the system to function properly, no key elements can be missing or lag behind. And FSMA won't achieve its purpose if the program is so inadequately funded that the system as a whole falters and fails. We want to be very clear that we cannot successfully build the new food safety system that Congress has called for without the new resources requested in the President's Budget. That is what's at stake in the fiscal year 2016 FSMA funding request.

#### CONCLUSION

We appreciate your strong interest in food safety, Chairman Moran, and this committee's support to date for FSMA and its effective implementation. We look forward to continue working with you to make FSMA a success. We would be happy to answer your questions.

Senator MORAN. Commissioner, thank you very much.

Let me begin just by asking. You outlined the scenario by which these rules will be announced. What was the basis for their prioritization? Is there something about these two rules that make them more difficult, easier, more significant to pursue? What do we expect in the future?

Dr. OSTROFF. Well, I will just say that they are all important. The preventive control rules are probably amongst the most important of all of these rules, and they are the ones that are expected to be implemented first. And so these had the priority to be issued. And the other ones will come shortly after that.

Senator MORAN. And the process you have been through will be the same process for the next promulgation?

Dr. OSTROFF. I will let Mike answer that. The essential answer is yes, we will issue these. The deadlines for these are set by court.

Senator MORAN. Court order.

Dr. OSTROFF. We are obligated to be able to meet all of them, and we will meet all of them. I can assure you of that.

Mr. TAYLOR. I will just add that as the Commissioner indicated, these rules are from a holistic package of standards that Congress mandated to frame this comprehensive preventive system, and so we have been through a dialogue with our stakeholders that has really addressed all of these rules because they have to fit together. And so we have to have a coherent package of regulations. So we are at the end of the process for all seven rules in terms of having gone through the notice and comment, public meetings, dialogues, and so now we are able to actually issue the rules in final. So the sequencing has something to do as well with just the capacity to get rules out the door and give a little breathing room between rules. So we are on track to get these rules out on that timeline, just as the Commissioner indicated.

Senator MORAN. Thank you very much, Mr. Taylor.

Dr. OSTROFF. So, Mr. Chairman, if I might.

Senator MORAN. You may.

Dr. OSTROFF. Mike just can make a couple comments about the implementation plan, and that may help to put some of this in context.

#### FSMA IMPLEMENTATION PLAN

Mr. TAYLOR. Well, again, this is a large topic, and I am sure your questions will draw it out in detail. But we are embarking on implementation and deeply cognizant of the challenges, the hundreds of thousands of facilities, and the complexity of supply chains. But we know that we can meet this challenge because we have got the alignment of stakeholders, we have done the homework, we have had the dialogue. And I think the thing that I would just provide at the Commissioner's suggestion is an overview. Some of the themes that we are pursuing undergirding the implementation that we think is crucial to success—and I think it is just crucial that we stick with these themes.

#### COMPLIANCE

First is this commitment, as we implement, to provide clarity through outreach and guidance about the new rules, what they require, and to be supporting of the industry in achieving what is expected through education, through technical assistance. We have said on any number of occasions that we will educate before and while we regulate, and we absolutely mean that. So that is the first theme, clarity and support for compliance.

#### INSPECTION

The second theme we need to do thematically, as you have indicated and the Commissioner indicated, is just fundamentally revamp how we conduct our inspections, how we conduct our oversight and compliance activities so that we are targeting our efforts based on risk and actively fostering and supporting voluntary compliance through frontline oversight that historically has been enforcement and reaction-oriented. Now it needs to be prevention-oriented and supporting compliance.

I always need to add the caveat. As much as we want to work with industry, if we encounter conditions where consumers are being put at risk, FSMA expects and has given us new rules to take swift action to protect consumers. But the goal has to be compliance in food safety not just enforcement as an end in itself.

#### PARTNERSHIPS

The third theme that I will emphasize, again picking up on what the Commissioner has said, is strengthening and expanding our partnerships with State agriculture and health departments. This is absolutely essential. We have a mandate from Congress to establish a national integrated food safety system. And we fundamentally understand that FDA cannot possibly implement this law successfully by itself. It has to work with our State and local partners.

And finally, I just reemphasize—and I think this is crucial—the commitment that I think we all need to have to this integrated, comprehensive implementation of FSMA. This system is a system. It does not work if we tease out parts or delay parts or do not inte-

grate this in a holistic way. I think the import safety provisions are particularly a crucial part of this overall system of prevention. This is how we will get a level playing field for U.S. producers. We will meet the expectations of consumers that the food that is imported into this country is as safe as food that is produced here.

So these are themes that we hope to come back to, and we want our feet held to the fire with respect to pursuing this in this way. And I think if we do this, as daunting as it may seem with the hundreds of thousands of folks we are seeking to bring into a new system, we think we can do it sticking with these themes.

Thank you, Mr. Chairman.

Senator MORAN. Mr. Taylor, thank you.

Commissioner, your charts, particularly this one—what is the explanation? What is the cycle that occurs here. You said there were ups and downs. We have had reductions and increases both. Is there a cause and effect that you could describe to me why that is with one particular pathogen?

Dr. OSTROFF. Yes. Well, it is a good question. I think if you look over here, one of the other things that I think is quite notable from this particular graph is that for many of these pathogens, that many of the reductions, the reductions being the ones that you see that are lower than one, occurred during the very early years of implementation of some new food safety activities in the late 1990s. And really if you follow that along into the 2000s, for many of these it has really been incredibly flat.

Now, I think it is important to recognize that food safety and foodborne illness is an incredibly dynamic area. We have new challenges. We have an incredibly diverse food supply. I would venture to say it is much, more diverse than what we had back in the 1990s when we started keeping some of these statistics. Increasingly the proportion that comes from overseas has grown. Sort of the locally grown phenomenon has increased over that time period. And so there are a lot of things that are challenging the food safety system and influencing the occurrence of foodborne disease. But I think the bottom line is that as these trends have changed over time, we have basically been treading water, and it is time that we no longer tread water, that we actually do things that we know will work to make these numbers look different as we go forward.

Senator MORAN. And you believe FSMA will bend that curve?

Dr. OSTROFF. I believe FSMA will bend that curve. I mean, if you look at several of the major food safety problems that we have experienced this year, including the most recent one that we have seen with the cucumbers that were imported from Mexico, the various provisions that are in FSMA are specifically designed to address the challenges that we have seen in all of those outbreaks. And so we should be able to influence not only the outbreaks that are occurring but more importantly I think the day in and day out sporadic foodborne illness which forms the bulk of this particular data.

I do also think it is important to say that while we certainly believe that all of the activities encompassed under FSMA will work to drive these numbers down, it does not absolve consumers of doing the right thing once this food gets into their kitchens because a lot can happen even if the food as it comes into the kitchens is

safe. And so it is a comprehensive approach that must be taken to assure that foodborne illness does not occur.

Senator MORAN. Let me turn now to Senator Merkley.

Senator MERKLEY. Thank you, Mr. Chairman.

Dr. Ostroff, in your testimony, you note that FDA's strategy is taking an "educate before and while you regulate" approach. I note that you are currently working on guidance documents. This is very important considering the first two final rules are about 1,500 pages, so a substantial amount. And these guidance documents will be critical for businesses to understand and comply with the new law and they need to be timely. So folks in Oregon are asking when these documents will become available, and I will just give you a chance to answer their question.

Dr. OSTROFF. To best answer that question, I am going to turn to the person who is actually writing them.

#### GUIDANCE

Mr. TAYLOR. I have a large and able team back home writing them as we speak. Guidance is absolutely essential to the success of implementing these rules, and we are investing a lot of resources in that now. We have been doing that even as we have been preparing the rules themselves.

One thing I would note in the 1,500 or so pages, this is 8 and a half by 11, double spaced, but the vast majority of those pages are a preamble, are themselves guidance and explanation of what the rules actually mean and how we expect them to be applied. And so that is the first place folks should go to really get an understanding of what the codified rule language itself actually is intended to mean in practice. But that is just the first step in guidance.

So as you know, we are developing a number of guidance documents, some of which are the key foundational ones. So there will be a comprehensive guidance on the human preventive controls rule that will be almost kind of an operator's manual for those who are not yet implementing modern preventive controls like many in industry already are. For those who are not there yet, this is going to be a very helpful operating guide essentially for implementing the rules.

They will be doing a similar guidance for animal food, at least a similar guidance for both the animal food preventive controls—

Senator MERKLEY. I am just going to cut to the chase and say I am glad it is going to have this guidance. When will folks see that?

Mr. TAYLOR. These major guidances will be coming out early to mid next year, well ahead of folks' obligation to comply.

Senator MERKLEY. Great.

Mr. TAYLOR. And they will be open for comment. It will be an ongoing process of dialogue, but our best thinking will be out there in a timely way for implementation.

Senator MERKLEY. Okay, great.

#### FSMA AND FOREIGN SUPPLIERS

I have heard from constituents and that there are concerns that foreign businesses may not be as closely monitored as U.S. busi-

nesses, and consequently there might be greater risks from foreign products than from U.S. products. And additionally, it could put U.S. businesses at an economic disadvantage because of the clients' costs for FSMA.

In your testimony, you state that FDA cannot credibly hold domestic producers to the new standards if we are not doing the same for importers and their foreign suppliers and vice versa. So I know you are aware of these concerns. And this all may get further discussed when the foreign supplier verification rule is finalized next month. But to the degree you can tell us now, how will the FDA adequately ensure the safety of foreign food products, and will that oversight be as rigorous as the oversight for U.S. businesses?

Dr. OSTROFF. Well, I am going to allow Mike to give you some of the details. But all I can say is that one of the fundamental tenets of FSMA is that we assure that the safety of foreign-sourced food is equivalent to domestically produced food. I think that we have that obligation to create that equity. We know that to certain degrees our tools available to us to be able to deal with imported food have been limited, but this rule, this law will not successfully work unless we can assure total equity between food that is produced overseas with food that is produced domestically. And one of the critical elements of that is that the importers that are bringing this food into the United States assure that the procedures that were in place to produce that food are equivalent to the procedures that are in place for food that is produced domestically.

Let me let Mike give you some more detail.

Mr. TAYLOR. So Congress did provide really a multifaceted toolkit for strengthening import oversight, and the Commissioner has referred to the central, really the foundational part of that which is this foreign supplier verification and requirements so that importers will now, for the very first time, have a food safety responsibility to be accountable to us for knowing their source of supply and verifying that those foreign suppliers are producing under our standards. That is a paradigm shift if we can implement it well. It is combined, though, in the design of Congress with much more overseas presence by FDA, so more foreign inspections, more partnership with foreign governments, more investment in foreign food safety capacity where that will contribute to food safety here. We think this toolkit, if implemented properly, will work to provide that equal rigor. The question is implementation. Can we make the investments needed to carry this out as intended?

#### FOREIGN INSPECTIONS

Senator MERKLEY. So, Mr. Taylor, you mentioned the foreign inspections, and FSMA mandated 600 inspections in 2011, with a doubling of the previous year's inspection level for the subsequent 5 years, which would mean that in fiscal year 2015, we would have about 19,000 foreign inspections. And in fact, I believe that the Department plans to only conduct about 1,200. So 19,000 under FSMA versus 1,200. This lack of foreign inspections is adding to the concern that really different standards are going to be, if you will, practiced in foreign countries because there are not enough inspections to hold them accountable. Your thoughts on that?

Mr. TAYLOR. You put your finger on a huge challenge, and that is how do we target our resources with the resources we get to implement this law effectively for food safety. So we have increased our foreign inspections from less than 300 before enactment to in the 1,200 to 1,400 range currently. And those have been very important. But they are part of the larger system. And so the inspections are not inherently preventive in the sense that the foreign supplier verification program requirement is. So in terms of priorities for implementing the import system, we have got to get 88,000 importers up to speed in terms of doing their prevention-oriented verification. And so that will be a priority for funding.

We would like to do more foreign inspections, but we also think that we can leverage the inspection activity of foreign governments through mechanisms like a systems recognition tool that we have developed where for countries who have advanced food safety systems, we want to recognize that and be able to rely, engage in a mutual reliance sort of relationship where we can rely on their inspections and not duplicate their efforts. So there are multiple elements of this.

One of the major investments we have made over the last few years with increased funding from Congress is to strengthen our foreign offices overseas, which again are going to play a vital role in us building the relationships with foreign governments, outreach to foreign industry, all those things that we can leverage our limited resources to maximize prevention activity overseas. So we would love to continue the dialogue about how we increase the inspection numbers, along with these other activities.

Dr. OSTROFF. The one thing that I do have to emphasize, though, is that part of the request that we made in fiscal year 2016 for the full amount of funding, which was \$109 million, was to be able to assure that we could carry out the requirements, especially for foreign-produced food. You know, with a number that is significantly lower than that, we will be challenged—I think that there is little question—of being able to implement the various rules that will be coming out over the coming months in the way that we envision that they need to be rolled out.

Senator MERKLEY. And I think one of those areas that the funding is impacting the United States is in filling those foreign offices. You mentioned an increase, but I believe the vacancy rate right now is 40 percent of foreign offices are vacant. Is that primarily a funding issue or a prioritization issue?

Dr. Ostroff I will say that it is expensive for us to be able to place people overseas. However, actually placing people full-time in these offices is only one of the strategies that we have been using to carry out those responsibilities. So we do cycle in people for short-term assignments to be able to assure that we can carry out the things that we need to do in those locations.

Senator MERKLEY. Thank you.

Senator MORAN. The Senator from California, Senator Feinstein.

Senator FEINSTEIN. Thank you very much, Mr. Chairman. I really appreciate the opportunity to talk with you, Commissioner, for a few moments.

I have long been interested in this, actually before my colleagues came on, and have tried to be helpful in getting more ag inspectors at our border. But that is a long time ago.

California, as you know, is a huge—it is the number one agricultural production State. Can you give me any percent or any measurement of Salmonella and Campylobacter in California-produced produce?

#### CALIFORNIA PRODUCE

Dr. OSTROFF. That probably is not a number that I would have off the top of my head. Given my extensive time at the CDC, I am pretty familiar with the systems that they use to collect the data, including the data that went into the FoodNet report, in which California is one of the participants in that system. And so there are data that are broken out by State for the various FoodNet sites in terms of the incidence of some of the pathogens that you see on these lists. I cannot tell you whether or not it is done on a commodity-specific basis.

Senator FEINSTEIN. Okay.

#### CUCUMBER SALMONELLA OUTBREAK

Now, the latest Salmonella outbreak for us is the cucumbers imported from Mexico. And I gather that is 418 illnesses across 30 States, and we have seen the most illnesses of any State, 89 illnesses, 17 hospitalizations, and one death. I am concerned that year after year, the Centers for Disease Control reports that the United States has not made progress in reducing the number of foodborne Salmonella infections that occur.

I was listening and also reading your comments how these new food safety regulations, FSMA, that you are finalizing will prevent outbreaks from happening with specific products. Take the cucumber as an example. How will you work it both at the border and in a foreign country with the farm operation in Mexico that is producing these crops?

Dr. OSTROFF. Well, I will preface my statement by saying that that particular outbreak is still under investigation, and so we do not know all of the specific details that may have led to it happening.

But having said that, I think that if you think of two of the major outbreaks that we have experienced this year, one of them being the Salmonella associated with the cucumbers and a few months earlier a parasitic pathogen, Cyclospora, that was associated with cilantro that also was imported from Mexico, you know, there are some themes about the quality and implementation of measures to prevent problems from occurring in the first place and that is at the heart of what it is that we are trying to accomplish under the produce rule. And so that produce rule establishes a number of standards that producers overseas that and producers domestically need to adhere to.

Senator FEINSTEIN. Could you give us an example of the standards?

Dr. OSTROFF. Well, you know, some of them are the water that is being used to irrigate the crops. One of them has to do with the access of animals to various locations. There is another aspect that

deals with the hygiene of the workers that are working on these particular farms. And so it is a whole variety of requirements that will be in place under the produce rule that any producer who is importing food into the United States will be expected to meet.

Mr. TAYLOR. If I just may add. The difference FSMA will make is that we have known for years what these practices are, and FDA has provided guidance, voluntary guidance, but there have been no enforceable standards, whether for domestic or foreign producers, and thus no accountability for doing the right thing. And so what FSMA does is create enforceable standards and then also verification that those standards are being met. I mean, it is that simple, but it is a profound difference from where we have been before where it was incumbent upon FDA to find and react to the problem in the absence of clear standards for prevention. It is a real game change that for cucumbers, that kind of example, will make a huge practical difference.

Senator FEINSTEIN. Right.

#### FSMA COORDINATION WITH USDA

Now, I gather produce is about 46 percent of foodborne illnesses, and that is under your jurisdiction, and the rest of it, meat, chicken, pork, is under USDA, if I understand that correctly. Do you coordinate in standards between the two of you or are the standards different?

Dr. OSTROFF. One of the critical requirements of being successful with FSMA is to be able to work closely with a whole variety of partners, and it is not only partners that are at the Federal level, but it is also down at the State and local level where a lot of the day in and day out work with farmers occur. And so, yes, it is very important that we work quite closely with USDA to ensure the success of what we do.

Senator FEINSTEIN. With produce—for example, I have had *Campylobacter*, and I know how serious it can be. And it was from eating not thoroughly cooked chicken. And so I asked my staff to look into it. Now, this is not your jurisdiction, but it is interesting to me that up to 40 percent of the ground chicken in markets may have *Salmonella*. And I talked to a large chicken grower in my State, and I said, what about this? And he said, well, everybody knows you have to cook chicken to 165 degrees until you eat it. I said, well, I did not know. And I do not think everybody knows.

So it raises the question of how these two agencies interact. I really think you have a good thing going in what I have read on FSMA, and I like very much how you are going about it. I worry very much about particularly chicken because chicken has become such a high item for people in terms of eating. And it does not seem to me that we make much progress year over year, year after year.

But with respect to this, what you mentioned, cilantro, cucumbers, ice cream, tuna, caramel apples, and these five outbreaks alone are almost 1,000 cases of illness and 12 deaths. Do you think that there is anything that USDA can begin to learn from FSMA? Do you think it is relevant?

Dr. OSTROFF. Again, we work very closely with USDA without question. Far be it for me to provide advice to them related to

things that we ourselves do not regulate. All I can say is that they too are working quite arduously in putting in place additional strategies to be able to address those products that are under their jurisdiction. And there are a lot of similarities to things that we are doing in FSMA to things that USDA is doing, you know, because again, from the consumers' perspective, if they end up with Salmonella, they end up with Salmonella and they are not so much interested—

Senator FEINSTEIN. That is exactly the point.

Dr. OSTROFF. [continuing] In what the source is as to what we do keep it from happening.

Senator FEINSTEIN. Right. And we have two big agencies. One handles the meat products and one handles the fresh produce products. And I have often wondered is that the best way to do it. I think you are taking action, and I am very pleased to see that.

#### ANTIBIOTICS IN PRODUCTS

I am also concerned about antibiotics in products and what has been happening in that human stream of consuming products that have antibiotics. Could you talk a little bit about that and what your agency is doing?

Dr. OSTROFF. Sure. As you know, this is also a very important aspect of food safety. We have had a multi-agency activity in place called NARMS (National Antimicrobial Resistance Monitoring System) that monitors not only the occurrence of various pathogens in a variety of food products, particularly meat that is sold at the retail level, but also monitors the patterns of antimicrobial resistance. We look at isolates that come from products that we regulate. USDA looks at isolates that come from products that they regulate, and CDC also incorporates information from human isolates of the same pathogens so that we can compare those patterns and look at those patterns over time.

As you know, we also have been working quite hard to be able to address the issue of antimicrobial resistance from foodborne pathogens. That is a whole other large component to their activities, especially by reducing the use of medically important antibiotics used in food-producing animals, particularly when used for growth promotion purposes. And so we have put out a number of guidances and rules specifically designed to address reductions in the use of antibiotics for those purposes. This has been a multi-year process to put those rules in place. We have done this on a voluntary basis to have all of the marketers of these antibiotics for use in food animals make labeling changes to remove growth promotion as an indication for the use of these antibiotics, and they have all voluntarily complied. The phase-in period to make those changes in the labels is to start at the end of this year. So we would look to see changes start to occur as a result of those practices.

And the other very important point of those requirements is to make sure that the use of those antibiotics for other purposes is under the direction of a veterinarian.

So both of them I think will be very helpful in terms of addressing the problem.

Senator FEINSTEIN. Thank you very much, Commissioner.

Thank you, Mr. Chairman.

Senator MORAN. You are welcome, Senator Feinstein. Thank you very much.

Just to educate myself in a more general way, let me raise a couple of topics that are a result of the questions and the testimony.

#### FOOD ILLNESS DEATHS

One of the things I wanted to ask about is the cause of death. You cite the CDC statistics, the 128,000 hospitalized, 3,000 die related to foodborne illness. Is there a breakdown of those deaths or hospitalization related to consumer preparation versus the food that was tainted prior to preparation? Do we know where the cause lies with the consumer versus the provider?

Dr. OSTROFF. It is not a very easy question to answer, especially when you are sometimes talking about a relatively long period between the time that the exposure may have occurred and when certainly the illness occurs and when the death occurs.

Having said that, we deal with a whole variety of different pathogens, some of which deal with items that are supposed to be cooked. Sometimes you are dealing with raw commodities like in the produce space. And so ultimately in most instances what you want to try to do—and I think what FSMA is designed to do—is to try to keep it from being there in the first place. And I think if you can successfully do that in many of these commodity areas, then you will successfully be able to have an impact in reducing these problems from occurring.

Senator MORAN. So there is a reduction that could occur in the likelihood of the problem that reduces the importance of consumer preparation of the food item.

Dr. OSTROFF. Let me just say without question that you never want to send any suggestion that consumers can become lax in the way that they handle their food because I do not think that we would want to ever send such a message. I think what we do want to do is to be able to enhance consumer confidence that the food that comes into their kitchens does not contain pathogens—

Senator MORAN. That was very artful. I will reask my question which would be there is no way—is there, Dr. Ostroff—that consumer preparation is not important regardless of what arrives in the consumer's home.

Dr. OSTROFF. You said it perfectly.

Senator MORAN. Thank you.

#### DOMESTIC AND IMPORTED FOODS

You indicate—well, first of all, I wanted to follow up on Senator Merkley's point about imported food versus domestic food. And he was asking for equity. An indication that you had indicated in your testimony that there is an importance to making sure that there is not an economic disadvantage to domestic producers. There is not a double standard I think is the way we would say it in Kansas. Does that double standard exist today? Is there a difference in the nature and the likelihood of foodborne illnesses from imported food versus domestic food?

Dr. OSTROFF. Since I have been answering those through the questions, I am going to turn that one over to my colleague.

Mr. TAYLOR. I think the answer is that under current law pre-FSMA, but also under FSMA, the standards are the same. I mean, Congress has made it very clear in FSMA that the same standards are to be applied. The same safety is to be achieved whether foreign or domestic.

The real difference and where there is a different challenge is in the ability to verify that those standards are being met, and we have very different challenges with imports than we do with domestic because we have an inspection force here. We can legally go into facilities. We can directly hold firms legally accountable. We have a whole set of relationships with the States who go into these facilities all the time. We can really cover that. There is no amount of foreign inspection that Congress will ever pay for us to do that would provide a comparable level of oversight through inspection overseas. And so that is why we have got this multifaceted toolkit of foreign supplier verification, more foreign inspections but very much collaborating with foreign governments. So the difference is really not so much the standards. They are the same standards. The question is how do you verify. And the imports provide a different verification and challenge than domestics.

Senator MORAN. And, Mr. Taylor, under FSMA the ability to enforce those standards is going to, in large part, rely on the certification of those who are importing food that their providers, their foreign suppliers, are in compliance.

Mr. TAYLOR. Well, that is the foundation for the new system because the U.S.-based importer is legally directly accountable to us. We can hold them legally accountable for doing that job properly. So that is where we have the direct legal handle. But then we can go over and again inspect foreign facilities. If we see a problem, we can keep that food from coming in. We can work with foreign governments again to foster good practices and to rely on their inspection activity. But, yes, the direct legal accountability for imports, in terms of private sector responsibility, is on that U.S.-based importer. So that is why that foreign supplier rule and its proper implementation is just so foundational.

Senator MORAN. What does that mean the importer is most likely to do to be able to sign that certification? What is that company going to do in a foreign country to make certain that when they attest that standards are being met, that they are actually being met?

Mr. TAYLOR. So under the regulation that we have proposed and you will see coming forward—and I am not here announcing the final content of the regulation, but I think the elements of it are evident from the proposals that we have put out and a supplemental proposal that we put out last year. But the whole idea is that—and again, this is just following the congressional mandate—the importer must have a program, a documented program where they have identified their suppliers, they have come to understand their suppliers' capabilities for food safety, they have approved their suppliers, they know the practices the supplier is undertaking, and they look at records. And under some circumstances, when justified by risk, because it is intended to be a risk-based foreign supplier verification program, we would envision the U.S.-based importer doing an audit, actually having an audit conducted

of that foreign supplier and on site onto that foreign producer. So it is having a real program that we can then audit and then, obviously, go behind that and sample product when it is coming in, go behind that and actually inspect the foreign facility, if we choose to. But it is that accountability for the importer that is the new feature that is so crucial.

Senator MORAN. The word “audit” has a different meaning than the word “inspect.” Is that true?

Mr. TAYLOR. Yes.

Senator MORAN. So when the importer is auditing, that importer is not inspecting. They would not be doing the same thing that an FDA inspector would be doing in a foreign country.

Mr. TAYLOR. Well, it is different because when you talk about inspection where we are used to going in and looking at facilities and conducting a physical exam of a physical place—the “audit” term that we are using applies to auditing the program, checking the records, being able to get confidence from examining the records and talking to the importer that they know what they are doing and they are doing the right thing. And so in that sense, it is a very records-intensive audit activity that will be at least a major component of ensuring this is being done properly.

Senator MORAN. Mr. Taylor, thank you.

I have more questions, Senator Merkley, but maybe a way to accommodate your schedule is to turn now to you, and if you are unable to stay for my final round, I would not be offended.

Senator MERKLEY. Thank you very much, Chairman.

#### VIBRIO INCIDENCE

I wanted to draw attention to the report that you have all displayed, the 2014 Food Safety Progress Report. For folks who are numerically challenged, you have boiled it down to happy faces, grim faces, and very unhappy faces. And the unhappiest of all is the face representing Vibrio. And over on the other chart that you have provided, you show that while every other disease has decreased since the 1998-till-now time period, there is one disease that has increased in incidence and that is Vibrio. What is the story? What particulars should we know about the challenge this disease represents?

Dr. OSTROFF. Well, Vibrio can also be a significant disease. It comes in a couple of different forms. There are several different pathogens that are encompassed under the label of Vibrio, and they are, in general, associated with seafood products. Now, I think it is important to put in context that in terms of the overall numbers, the number of illnesses associated with Vibrio was actually quite small and certainly a very small fraction of what we see in the United States from either Salmonella or Campylobacter. Some of this is associated with actual spread of Vibrio. In some instances, it was largely confined to certain areas of the country, and because of movements that occur with emerging diseases, it spread to other areas where it traditionally has not been. But it is a trend that we have been seeing particularly along the east coast.

Senator MERKLEY. I was reading an article recently about the ponds where shrimp are farmed on land in Asia and where massive amounts of antibiotics are used to control the various diseases that

are rampant in those ponds. Is that import of shrimp from these farms one of the factors contributing to the *Vibrio* expansion?

Dr. OSTROFF. I would have to get you specific information about whether or not that is contributing, but by and large, to my knowledge, most of the *Vibrio*-related illnesses are not associated specifically with imported shrimp.

[The information follows:]

While *Vibrio* related illnesses have been increasing in the United States in recent years, investigations conducted by state and local health departments have associated these infections with consumption of raw oysters and other raw forms of molluscan shellfish in the week before illness.<sup>μ</sup> A summary of these infections, including their recent increased recognition along the Atlantic coast, can be found on the website of the Centers for Disease Control and Prevention at [www.cdc.gov/vibrio/investigations/index.html](http://www.cdc.gov/vibrio/investigations/index.html).<sup>μ</sup> *Vibrio* infections are most common during warmer months when the organism is more prevalent in the marine environment.<sup>μ</sup> Infections can be greatly minimized by consuming only thoroughly cooked molluscan shellfish.

Senator MERKLEY. Thank you.

#### SALMONELLA IN PEANUT BUTTER OUTBREAK

Back when we were working on this bill, a young man and his father came out from Oregon to testify. The father was a police officer. The son, when he was 3—his name is Jacob Hurley. He had experienced a life-threatening case of *Salmonella* from contaminated peanut butter. And he was one among more than 700 who were sickened by contaminated peanut products in 2009. I believe that the company involved in that was the Peanut Corporation of America.

If we look back on that particular, well-publicized incident, how would the preventive controls rule that we have just passed have made a potential significant difference in the risk of that disease?

Mr. TAYLOR. So that is an unusual case in many respects in part because of the vast scale of the damage that it did and the thousands of products that had to be recalled because this firm was selling not only peanut butter in bulk but peanut ingredients that went out into thousands of processed foods. It was a catastrophic event for the food system.

It also involved intentional conduct by the owner and operator of that facility and the well-publicized subsequent criminal prosecution and conviction.

What FSMA will do, even in that situation, is provide a much stronger basis for inspectors, when they go into facilities, to not be reliant just on looking around at the facility conditions, and pre-FSMA with no access to the records of the facility, under FSMA we will have a much stronger ability as investigators to go into facilities and make assessments of the system and to be able to detect and find records that might actually document positive analytical results such as those that occurred in this particular case that would reveal a problem that needs to be addressed. So there is always going to be that rare instance where purposeful criminal behavior happens, and there needs to be swift remedies for that.

But I think even in these cases, we will be able to be more effective in our investigatory role in assessing systems and whether this sort of practice is going on in facilities that needs to be addressed very forcefully, and FSMA gives us new rules for addressing that

sort of situation forcefully. If we identify this sort of problem through inspection, under FSMA we can actually suspend the registration of that facility and shut the facility down administratively. And that is an important tool in these sorts of extreme cases.

Senator MERKLEY. So as you note, there were exceptional circumstances, leaky roof, mold, animal contamination, so on and so forth, kind of egregious behavior regarding some known problems. But in terms of the inspections you mentioned and the ability to kind of have teeth, that matters.

#### PREVENTIVE CONTROL RULE AND TRACE ABILITY

But there is another element of the preventive controls rule—I believe it is in the preventive controls rules—that involves developing a tracking system for ingredients that go into processed foods. And can you just comment on whether you believe that is going to make a difference?

Mr. TAYLOR. So FDA has historically—since the Bioterrorism Act in 2001 was enacted, it has had authority to require firms to keep records of where their incoming materials came from and where their finished products have gone, one up, one down recordkeeping. FSMA adds somewhat to our authority in this area by giving us the authority to set standards for how that firm connects the dots between the incoming and the outgoing. And so that will be a step, and that is a rulemaking that is underway to put that in place.

FSMA frankly put some constraints on FDA in terms of traceability because it precludes us from requiring essentially a farm-to-table pedigree or the kind of tracing that is done by UPS and FedEx. We are precluded from requiring that sort of use of technology to improve traceability. So from our standpoint, traceability is crucial. It is how we can investigate outbreaks much more expeditiously and get to the cause of problems and solve them.

But traceability is going to have to come into the modern era fully through public-private collaboration, finding ways to harness industry innovation with the support of us and dialogue so we can be sure whatever they do helps our investigators, as well as the firms themselves. But the work to be done yet is in that area.

Senator MERKLEY. Thank you very much, Mr. Taylor, Dr. Ostroff, Mr. Tootle. I appreciate it. Thank you.

#### FSMA COLLABORATION

Senator MORAN. One of the things I read in your testimony that I wanted to highlight and ask you to confirm to me how serious you are about this and how confident I can be that it will remain the policy, and that is, you indicate the approach to inspection is aimed first at fostering and facilitating compliance rather than finding and penalizing regulatory violations. That is a policy, in my view, that every regulatory Federal agency should adopt. The goal is to make improvements in cooperation with the regulated. And it seems to me—and we have had this in other agencies previously in which they seem to be that was the direction they were going, but over time, the joy of penalizing became too great and the attitude of cooperation disappeared.

Is there some assurance that you mean what you say in your testimony and that it will last as part of the nature of the Food and Drug Administration as it implements and enforces FSMA?

Dr. OSTROFF. Well, all I can say is that we do believe that the approach that is expressed in FSMA, which is to work collaboratively with regulated industry—and when I say “regulated industry,” we mean from the farm to the transport into people’s homes—that we work collaboratively to encourage them and to work with them to do it right. And we know that ultimately doing it right has tremendous impact. That is not to say because, you know, you always have to—and I am sure you are quite aware. There is the carrot and the stick. And we know that the carrot is quite an effective way to promote improvements in food safety, but that does not mean that we are not going to use the stick when we need to use the stick.

Mr. TAYLOR. If I could just add why I believe this will remain the policy over time regardless of who happens to be sitting in these chairs, partly we have put it in writing. We have made this commitment to the industry and to the public, and people support this externally. But equally important for your purpose, the people at FDA embrace this wholeheartedly. The people who are at the front line in our agency are public health people. Enforcement is a tool, and that has been the culture of the agency given the statute we have had and the framework for food safety, which has basically been an enforcement-oriented statute and program. But with FSMA, we are now public health at the front line, and our front line people love that. They would much rather be getting good food safety outcomes and doing public health than trying to rack up enforcement numbers. That is just not the fundamental mentality of that cadre of people, including the young people coming into the agency. It is an extraordinarily exciting time for them and for the whole agency. So I think the future is here in terms of the culture change that is going on, and we are working in many ways to institutionalize that and embed that in the practices of the agency.

Senator MORAN. Well, would it not be fair—I mean, I recognized when I asked that question, it may sound as if you are trying to take care of business or farmers, but is the reality not that we end up with a safer food supply system when this is the attitude?

Mr. TAYLOR. We know and you know, and if you talk to the people in the food business, it is just obvious the vast majority want to produce safe food at a personal level and it is in their intense business interest to do that. And so our whole strategy is based upon that assumption. We need to work with that vast majority who want to comply, support that compliance, verify that it is happening. And for those who are not complying, we will act swiftly and we will take whatever action is needed to protect consumers, and in these extreme cases like Peanut Corporation of America, invoke punitive remedies as a deterrent. But, no, I think working with those whose interest is aligned with ours on food safety is how we will get the best public health—

Senator MORAN. If I can respond to that before Dr. Ostroff speaks, in the world I come from in Kansas, the rumor of food disease or animal-borne diseases causes dramatic consequences to

farmers, to ranchers. It does not take an actual case. Just the thought that something may be wrong. And so I am certainly not opposed to strictly strongly enforcing penalties and putting bad actors out of business because they have a huge consequence certainly to the consumer and the safety of our food supply, but for those same business men and women, those same farmers and ranchers, they cannot afford financially to have the rumor the reality that there is something wrong with what they produce.

Mr. TAYLOR. And our strategic interests are fully aligned on that.

Dr. OSTROFF. And I think you are absolutely right. We know that the ramifications from foodborne outbreaks that occurred years ago still ripple through certain commodities.

The other thing that I will say is that the approach that we will be taking under FSMA is really a fundamentally significant change to the way that we approach food safety, and it is really critical because a number of things that are encompassed in the funding request that we have made to Congress is designed to ensure that up and down the system, we can reorient the workforce to be able to implement the things that you were saying in terms of being able to work collaboratively with industry, being able to educate industry, and being able to oversee and ensure that what they are doing is up to standards takes resources. And I do not know any other way to say it. And we do know, without question, that unless we receive the total amount of the request, that something is going to have to give in some aspect of what we are doing.

Senator MORAN. You could not help yourself.

Dr. OSTROFF. I could not help myself.

Senator MORAN. And I will be happy to visit about that topic. Let me finish up a couple other items.

#### STATES ROLE IN FSMA IMPLEMENTATION

When it comes to the State of Kansas, the State of Oregon, the State of California, what will the role be for those States as a result of FSMA and its implementation? What happens different at the Kansas Department of Health and Environment?

Dr. OSTROFF. Well, the approaches that are being taken at the Federal level—those same types of changes will also occur at the State level. The States and localities are really very critical partners in implementing FSMA as it is designed to be implemented. They are our front line eyes and ears. They carry a lot of the workload in not only working with their regulated industries at the State and local level, but particularly in certain areas. And the one that comes to mind most is the produce rule. We will look very much towards working with the States to be able to provide the type of front line support to all of the farmers within their States to be able to appropriately implement the new requirements for FSMA. And so they are really critical to the success of this endeavor.

#### ANIMAL FEED RULE

Senator MORAN. Let me ask one question related to the animal feed rule and contract farmers. Doctor, you indicated—Commissioner, you indicated to me that in advance of this hearing, that what I was going to hear from the folks out there in that world

would be all requests to make sure that Congress appropriated sufficient funds to implement FSMA, and that you had worked your way through many of the challenges and had a lot of input from stakeholders, as you described. And I appreciate that, and it seems to me that that is in large part the reality.

One area that I have heard concern about is the definition of what a farm or farmer is. And you are shaking your head and so maybe I do not need to describe the issue. Is there something afoot that I ought to know about the direction that you are going? What I have heard, that there is concern from farmers who have no involvement in anything other than raising the livestock, the animal, that FSMA will affect their operations as well when all the processing and everything occurs downstream. And in fact, the feed, most importantly, is not grown or provided by them. It is provided by upstream buyers of those they have contracted with. This is an issue—have I described it adequately. You were once smiling. Now you are frowning.

Dr. OSTROFF. Well, no, because the specific way that a farmer is defined is really critical to certain parts of these rules, not only the preventive controls but also to the produce rule. And so we have worked quite closely with those that will be impacted by this rule to make sure we can get it about as right as we possibly can.

I will ask Mike because I know he has been immersed in this particular issue for the last several years.

Mr. TAYLOR. I do know the issue very well, and the fact that there is presumably still some folks who have some concerns just shows that there is an exception to every rule—but stakeholder support for the rules.

But I think that what you are talking about is the situation where there are vertically integrated poultry operations where a Perdue or a Tyson will own the chickens. They will manufacture and own the feed. They will provide it to contract growers who own—

Senator MORAN. The growers only grow.

Mr. TAYLOR. The growers only grow.

The growers—if they have a concern that they are affected by this, I have not heard that and I do need to hear that. The affected party is the operator of that feed mill, that is not being managed on or by a farm operation but rather by this big vertically integrated poultry enterprise. That feed mill is subject to the animal feed preventive controls rule. The requirement is very practical and risk-based and so do not address issues that do not need to be addressed in terms of ensuring the safety of animal feed. But those feed mills are subject to preventive controls. If the poultry operator or any farmer—and this is the common practice for poultry—is growing or processing their own feed on their farm in their feed mill for their animals, that is part of the farm operation and would not be subject to the preventive controls rules.

So I would be happy to engage whoever has the concern and connect them with our Center for Veterinary Medicine and work through whatever the question is. But that is basically the way the rule—

Senator MORAN. You answered the question better than I asked it, and I think that is the assurance that they were having to hear.

Mr. TAYLOR. Okay. Well, again, I am happy to talk to them if that would help.

#### BUDGET REQUEST

Senator MORAN. Let me talk just a moment about the appropriations process. And I indicated in my opening statement this will continue to be a priority certainly of mine and I think of this subcommittee. And you mentioned specifically the amount of money that the President's budget requests and our ability to meet that at this point has not occurred. But we worked hard to put more money into FSMA implementation as we prioritize within the dollars that we have within our jurisdiction. And if those dollar amounts change, we are interested in reviewing and reprioritizing based upon what the needs are of FDA and others to try to make certain we make the right priority decisions.

But let me ask a couple of things about how the money has been spent in the past. As I indicated in my opening statement, the number, I believe, is an 8-percent increase over the last 5 years for implementation of FSMA at FDA. Mr. Tootle, am I saying that correctly?

Mr. TOOTLE. I think it is 4 percent, sir.

Senator MORAN. Of course, you do.

#### FSMA SPENDING

Senator MORAN. Well, let me ask how that money has been spent in implementation and how has it been allocated. Is it across food safety inspections, foodborne disease surveillance, detection? How have you decided how to spend that money over the past 5 years? And I will consult with my expert.

Dr. OSTROFF. So the total amount since 2010 that has been allocated specifically for FSMA—I believe the number is approximately \$162 million over that time period. It has been used in a whole variety of ways, but as you probably recognize, there has been a tremendous effort on our part to be able to appropriately lay the groundwork to get these rules to a place where those rules are both implementable and will work. And that is no mean task. As you know, we have had tremendous numbers of outreach activities to the various stakeholder groups. There have been somewhere in the range of 600 or so meetings that have occurred, either public meetings, interactions with regulated industries, various trade associations. As you know, we have walked facilities and farms from one coast to the other. There has been a significant effort to actually do all the writing that it takes to get these rules to the place where they were. As you know, we issued a number of supplemental rules. And so that has heavily contributed to a lot of the resources that we have used to get to the point where we can actually get to where we are now, which is to start implementing.

Mr. TAYLOR. In addition, there are a number of programmatic and capacity investments that we have made that I think are very significant as well. Some of it includes technical staffing, increasing technical staffing at the agency, so we can support the industry, our State partners, our own inspectors as they implement this. So this is at our Center for Food Safety and Applied Nutrition principally. We have doubled the investment in the States to close to

\$50 million over the last few years. We have been able with the resources we got, including these increases, to meet the FSMA mandate for high-risk inspections, the frequency mandate, and exceed that and do that earlier than expected. We think that has been an important part of getting ourselves in a position to succeed under FSMA.

And then the import area has been an area of investment. We have significantly increased the number of inspections, as I mentioned. We have expanded the foreign offices, things we have talked about. So there have been some significant programmatic investments in capacity for ourselves and the States to be ready to implement FSMA. It is part of an ongoing sort of buildup so we can succeed going forward.

Senator MORAN. Thank you, Mr. Taylor.

Mr. Tootle, it is apparently one of those circumstances in which both are right.

The desired outcome has been achieved. Food has increased by 8 percent, FSMA by 4.

#### REPRIORITIZING FUNDING

I think this is my final question. Is there any opportunities—let me ask that differently because there has to be. As you implement FSMA, are there opportunities for reprioritizing existing spending that that spending is no longer necessary because you are headed down a different path than the way the FDA operated in the past? So are there any savings to occur as a result of the implementation of FSMA?

Mr. TAYLOR. My Commissioner is looking at me, so I will say something.

Dr. OSTROFF. Because my short answer would be no.

Mr. TAYLOR. I think I am going to give yes. That is a no because I want to try to explain, though. If you look at the overall funding of the foods program, about three-quarters of it pre-FSMA goes into the field based activities that relate to food safety but doing it the old way. What we are talking about is adding frankly incrementally to that base resource so we can reorient, redeploy all of that resource to doing food safety in the way envisioned by FSMA.

Senator MORAN. It is not the best answer.

Mr. TAYLOR. I wanted to get credit for the fact that we are not just continuing to do all the old stuff and then add on the new thing.

Senator MORAN. That is the nature of my question.

Mr. TAYLOR. Yes, sir. And the answer is we are redeploying but it does not mean we can stop spending the money that is needed to support that workforce. We have to, in fact, invest in it so it can work in this modern prevention-oriented way in a much more sophisticated regulatory framework. So, yes. So it is redeployment as opposed to adding on resources on top of resources that are still deployed doing the old thing.

Senator MORAN. That is what I want to hear. And since you, Dr. Ostroff, wanted to answer no, I will give you the opportunity to say yes.

Is the reality not, is the truth not that we can now—as we do things differently, you redeploy assets, resources that were directed in the old way of doing business to the new way of doing business?

Dr. OSTROFF. So this is not going to require fewer people to be successful. It is just going to require that those people do things differently than they have been doing them, but the people that we need to be successful for FSMA will not—you know, we are not going to have people go away. And in point of fact, given the various responsibilities that we have under these rules, we need every single one of those people to be successful in implementing this. So from the standpoint of what we have been doing with our field force and what we have been doing with our laboratories, those responsibilities do not disappear under FSMA.

Senator MORAN. Dr. Ostroff, thank you for your testimony. Mr. Taylor, thank you for being here. Mr. Tootle. Anything you would like to make certain that is included in the record before we close this hearing?

Dr. OSTROFF. Well, I will just close by saying I am the eternal optimist. The request that we made for this fiscal year for FSMA implementation from my perspective is absolutely critical to its success. And to make this have its maximal impact, which we hope that it will have to change some of these graphs that you see here on the right and the left, every component of that request is vitally important to the success of this endeavor. And so we will have some incredibly difficult choices to make if we cannot get that particular request. And so I recognize that you have been an ardent supporter of the success of FSMA, and we certainly are totally appreciative of the efforts that you have made to this point, and we are very, very appreciative of the resources that did show up in the subcommittee's and full appropriation for FSMA implementation. All I can say is that there will be some significant shortfalls that will result with that particular number, which will make it very challenging for us to be able to put in place right from the get-go what we need to do to be successful in this endeavor.

#### ADDITIONAL COMMITTEE QUESTIONS

Senator MORAN. Doctor, thank you very much. I appreciate your testimony. Thank you for being here. I appreciate the presence of my colleagues. And for members of the subcommittee, either those that were here or who were not, any questions that they would like to submit for the record should be turned into the subcommittee staff within 1 week, which is Wednesday, September the 23rd, and we would appreciate having a response back from FDA within 4 weeks subsequent to that point in time.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

#### QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

##### PRODUCE SAFETY

*Question.* Please provide a food safety risk rationale why FDA concluded that Produce Safety provides adequate regulatory oversight for on-farm packinghouses that pack any amount of produce not grown on the same farm, and “secondary activities farms” that are majority owned by the primary production farm(s) that pro-

vide a majority of the produce packed, but an off-farm packinghouse that performs the same activities on the same commodities requires the added complexity of the Preventive Controls rule if more than a majority of fresh produce packed is not grown by the packinghouse majority owner(s).

*Answer.* Produce packing houses that fall under the new farm definition and pack covered produce would be covered by the forthcoming produce safety rule. Produce packing houses that do not fall under the new farm definition would be facilities covered by the preventive controls for human food rule. We recognize that this means that establishments performing basically the same activities will be governed by different regulatory regimes. We are limited by our statutory authority. FSMA sets up a dichotomy, where farms packing and holding covered produce are subject to the produce safety rule, with its regulatory structure, and facilities required to register are subject to the preventive controls for human food rule, with its regulatory structure. We have expanded the farm definition as far as we think we can, while still reflecting what a farm is in the real world.

However, we expect that the specific steps necessary to ensure the safety of produce would generally be the same for on-farm and off-farm packing houses. For example, the preventive controls rule allows a packing house, for produce covered by the produce rule, to comply with the applicable requirements for packing and holding under the produce rule rather than to comply with the Current Good Manufacturing Practice (CGMP) requirements. In addition, although an off-farm packing facility would be required to establish and implement a food safety plan and establish preventive controls for food safety management components, we expect that, in general, off-farm packing houses can look toward the produce safety rule for guidance as to what to include. We expect that an off-farm packing facility's food safety plan would focus on a few key preventive controls with counterparts in the proposed produce safety rule. For example, we expect that the food safety plan for an off-farm packing facility would include preventive controls such as maintaining and monitoring the temperature of water used during packing. We also expect that an off-farm packing facility would establish sanitation controls to address the cleanliness of food-contact surfaces (including food-contact surfaces of utensils and equipment) and the prevention of cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces. These preventive controls have counterparts in the proposed produce safety rule.

#### ANIMAL FEED

*Question.* In regard to the Rule for Preventive Controls for Animal Feed, the FDA has indicated it did not intend to regulate farmers/growers of animals. However, it appears that the Animal Feed rule will cover a significant number of contract farming operations, even though the owners of the animals have 100 percent control over feed manufacturing.

How many feed mills and/or farm operations do you expect this rule to cover?

*Answer.* The Preventive Controls for Animal Food (PCAF) rule applies to all facilities that are required to register with FDA under section 415 of the FD&C Act because they manufacture, process, pack, or hold animal food for consumption in the US. Farms are not required to register and therefore are not covered by the PCAF rule. Whether a feed mill is covered by the PCAF rule depends in part on whether it is considered part of a farm. FDA's Food Facility Registration database tracks the number of registered facilities. As of August 9, 2015, there were 5,919 domestic animal food facilities registered and 9,804 domestic facilities that were registered as human and animal food facilities. The 5,919 domestic animal food facilities are covered and likely a portion of the facilities that are registered to produce both human and animal food. The facilities that produce both human and animal food may choose to follow human food current good manufacturing practice and preventive control requirements throughout their facility instead of following the requirements of the PCAF rule for their animal food (as long as any hazards for the animal food are addressed). Within the total of domestic registered facilities, there may be some facilities that are subject to one or more exemptions from the PCAF rule or are subject to modified requirements.

*Question.* Are you going to prioritize regulatory oversight on the animal food rule, and does the agency plan provide guidance to clarify this issue?

*Answer.* Full funding as requested in the fiscal year 2016 President's Budget is necessary for FDA to implement all of the FSMA rules, including PCAF, in a holistic, risk-based way. FDA has been developing implementation plans for the PCAF rule, and we are also currently working on development of regulator training and guidance documents. FDA is planning guidance documents to help industry comply with the requirements of the PCAF rule. The first guidance will be for implementa-

tion of the Current Good Manufacturing Practices provisions, closely followed by a guidance document on human food by-products for use as animal food. FDA will make available another guidance document that will address the hazards associated with different foods and how to apply the preventive controls requirements. There will also be a Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.

#### IMPORT SAFETY

*Question.* How many foreign manufacturing facilities are there and what are the top countries that export to the United States?

*Answer.* There are approximately 118,104 registered foreign food facilities. The following table provides the top ten countries that export to the United States in order from most to least food import lines. The top two countries are Mexico and Canada.

Top Ten Countries for Food* Imports - FY 2015 (Oct 1, '14 - Sep 30, '15)			
Row Labels	Total Lines	Food Lines	% of Food Lines
Mexico	7,571,115	3,726,626	49.2%
Canada	5,103,980	2,992,169	58.6%
Italy	850,241	478,524	56.3%
Japan	690,756	395,139	57.2%
France	947,631	388,648	41.0%
China	6,430,589	283,680	4.4%
India	439,934	220,362	50.1%
United Kingdom	577,016	175,316	30.4%
Korea (the Republic)	324,230	166,355	51.3%
Thailand	437,755	156,707	35.8%
<b>*Food Lines include: Human Food, Infant Food, Dietary Supplements, Color &amp; Food Additives</b>			

*Question.* What is the process to inspect/approve products from these facilities? How does FDA interact with foreign governments, and their inspection regimes?

*Answer.* The process of inspecting foreign food facilities begins with the Center for Food Safety and Applied Nutrition (CFSAN), which identifies foreign facilities for FDA inspection based on risk factors including whether or not they produce high-risk commodities or employ high-risk practices in the manufacturing process. Specific foreign countries are not targeted for inspection unless there are specific disasters, events, or country-wide practices associated with production that may pose a unique risk. FDA foreign food facility inspections are conducted by dedicated foreign food inspection cadre/investigators, domestic food inspection investigator volunteers, and foreign office investigators based overseas. The Office of Regulatory Affairs (ORA) plans and conducts foreign inspections for U.S.-based investigators, whereas inspections conducted by overseas-based investigators are planned by the relevant FDA foreign office (FDA has investigators based overseas within FDA's foreign offices in China, India, and Latin America). Specific foreign inspections trips are planned based on firm location, availability, reason for inspection, and commodity. After the completion of a foreign inspection, FDA may take steps such as placing a firm's product on Import Alert, based on observed and documented violations. FDA regularly interacts with foreign governments and their inspection/regulatory regimes. When FDA intends to conduct inspections of facilities in foreign countries, CFSAN informs the foreign government regulatory authorities and invites the foreign authorities to observe the FDA inspections. ORA or an FDA foreign office provides the foreign regulatory authority with information that includes the timeframe of the inspections, the list of firms to be inspected, and final itineraries if desired. Foreign regulatory authorities often accept invitations to observe FDA inspections, which provide learning experiences for the foreign authorities.

FDA's India Office and the Indian drug regulatory authority will collect data pertaining to either regulatory agency's observations of the other's inspections in the future. This data-gathering exercise will facilitate data analyses for developing a better understanding of current inspectional and regulatory practices of each regulatory agency and developing strategies to better cooperate on matters of mutual regulatory concern.

The Latin America Office has conducted foreign inspections and environmental assessments accompanied by foreign counterparts. These activities are conducted in an effort to leverage our combined resources, ensure the application of standards, and increase regulatory capacity. During accompanied inspections, the foreign regulatory authority and FDA conduct concurrent inspections of an establishment. During the inspections, there is constant communication and discussion between the two authorities. We have seen certain foreign authorities take regulatory action on the spot when conditions that pose a serious risk to the health of consumers are encountered. Foreign regulatory authorities have taken their own samples and have ordered the destruction of potentially contaminated products. The same situation occurs when a collaborative/joint environmental assessment in response to a foodborne illness outbreak or a food contamination event is performed. If FDA subject matter experts find a major violation, foreign counterparts may be able to take immediate regulatory actions. They may also conduct a follow-up inspection at the firm to ensure that corrective actions were implemented.

The China, India and Latin America Offices have shared information, as appropriate, with regulatory counterpart organizations in China, India and Mexico after inspections in those countries. This has resulted in actions by the regulatory counterpart organizations based on violations observed by FDA.

In 2014, FDA signed the following arrangements with Chinese, Indian, and Mexican regulatory authorities that affect FDA's interactions with those authorities regarding food safety inspections:

- Two Implementing Arrangements with Chinese regulatory counterparts that outline cooperation regarding inspections of food and drug facilities in each other's countries. Since the signing of the two Implementing Arrangements, cooperation and the exchange of regulatory enforcement information have increased. The number of FDA inspections that Chinese regulatory counterparts have observed has also increased. Additionally, FDA received visas for new inspectional staff whose visas had been previously delayed.
- A Memorandum of Understanding (MOU) with Indian regulatory authorities that will improve cooperative activities in the area of food safety. The India Office also conducts quarterly meetings with Export Inspection Council (EIC) to advance the implementation of the MOU and share information for regulatory and/or risk-based decisionmaking.
- A Statement of Intent with Mexican authorities to develop and implement a Produce Safety Partnership that aims to achieve mutual confidence in one another's produce safety systems. Under the Statement of Intent, five working groups were established. Two of these working groups have focused on inspections: Exchange of Information and Training of Auditors/Inspectors and Outbreak Response. These two working groups have conducted thorough, in-depth discussions that have led to enhanced interaction when FDA conducts inspections in Mexico.

FDA's China, India, and Latin America Offices have also engaged in technical workshops with our foreign regulatory counterparts to strengthen the regulatory understanding and capabilities of inspectorates abroad.

- FDA's China Office has engaged with Chinese regulatory authorities regarding data integrity and compliance in the area of Low-Acid Canned Foods (LACF) by holding classroom training on FDA's regulations and inspection training at a facility. A total of 30 Chinese inspectors attended, including one inspector from each of the Chinese provinces that export LACF products to the United States as well as 10 inspectors and several managers from various Guangdong authorities' offices where the training was held.
- FDA's India Office partners with Indian regulators to train them on food- and drug-related issues and inspectional techniques, good manufacturing practices, and the detection of data integrity issues.
- The Latin America Office has facilitated participation by foreign regulatory officials/inspectors in courses provided by FDA's Office of Regulatory Affairs training component (ORA-U), thereby helping enhance the knowledge, skills and capabilities of foreign regulators, as well as helping them better understand the U.S. food safety system.
- FDA's Europe Office does not include investigators among its staff, yet it facilitates FDA inspections of facilities in Europe by cultivating and maintaining re-

relationships with regulatory counterparts in Europe and working with U.S. governmental agencies in-country with complementary missions, e.g., the U. S. Department of Agriculture's Foreign Agricultural Service.

In addition, FDA's overseas offices contribute to FDA's international inspections by analyzing reports/audits by foreign regulatory counterparts to aid in facility selection.

*Question.* How do you propose to support and build upon these efforts to open FDA offices in foreign countries? Could you provide more detail on the types of activities these offices should be carrying out, and what benchmarks we might use to measure the success of these activities?

*Answer.* Since 2009, FDA has operated foreign posts strategically located around the globe, including in China, India, Mexico, Belgium, United Kingdom, Costa Rica and Chile. The India and China posts have significant numbers of investigators in the foods/feeds and medical areas. The goals of the foreign posts include:

- Building FDA knowledge around the foreign competent authority's (CA's) capacity, the role industry(ies) plays in the country, and the dynamics between these two.
- Strengthening FDA linkages with CAs and public and private stakeholders for increased and more timely information and collaborative approaches to tackling issues of concern to FDA.
- Increasing awareness of foreign governments, industry and others about FDA regulatory requirements, as well as new legislation such as the FDA Food Safety Modernization Act and the Food and Drug Administration Safety and Innovation Act.
- Conducting FDA inspections and investigations in country, including for-cause and surveillance inspections. FDA encourages CAs to observe our foreign inspections, which provide learning opportunities for foreign regulators.

Measuring impact is a complex process(es). The Office of International Programs is developing metrics to benchmark and better measure success of these types of activities performed at FDA foreign posts. These could include the number of FDA inspections conducted in the country or region, but optimally would measure the impact of FDA inspections, workshops and other collaborative activities on the rate of violative products from the country or region and capacity of foreign regulators conducting inspectional work.

*Question.* What, specifically, are obstacles these offices face in monitoring foreign food production and foreign food safety systems?

*Answer.* The food safety systems in some countries are complex and involve multiple regulatory authorities at the central and regional/state/local levels. Responsibility for regulatory oversight may not be well-defined or able to be measured. Implementation of food safety standards and enforcement activities may vary significantly by region. Thus it can be challenging to monitor and, more importantly, understand the regulatory systems, regulatory capacity and national policy dynamics.

Language and cultural contexts are also challenges in building FDA knowledge around foreign food production and food safety systems, particularly given the difficulty of translating often nuanced policies written in a foreign language.

*Question.* What types of authorities and resources will those offices need in order to be effective?

*Answer.* FDA is currently evaluating if additional authorities and/or resources will be needed in fiscal year 2017.

---

#### QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY

*Question.* How has FDA worked with NIFA at USDA on outreach and training for FSMA? Do you expect that small local organizations will be able to compete for FSMA training dollars, both at USDA and FDA?

*Answer.* FDA and USDA's National Institute of Food and Agriculture (NIFA) have joined in a collaborative partnership to administer and manage the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program using competitive grants, with the goal of providing training and technical assistance to owners and operators of small and medium-sized farms, beginning farmers, socially-disadvantaged farmers, small processors, and/or small fresh fruit and vegetable merchant wholesalers, as mandated in Section 209 of FSMA. Community-based organizations (CBOs) are among the eligible entities to receive grant funding, and the requests for applications have specified that this program will provide significant opportunities for funding through subcontracts and for partnerships with eligible stakeholder groups who work directly with the target audiences.

The joint program will first award competitive grant funds that enable an award-ee to establish a National Coordination Center (NCC) for Food Safety Training, Education, Extension, Outreach, and Technical Assistance and then award grants for the establishment of four Regional Centers (RCs) across the country. The RCs will work with local communities to ensure that the training teams include representatives from non-governmental organizations, CBOs, cooperative extension services, food hubs, local farm cooperatives, and other entities that can address the specific needs of the communities they serve.

FDA issued a request for grant applications for the establishment of the NCC on December 31, 2014, which closed on March 16, 2015.<sup>1</sup> FDA has awarded the International Food Protection Training Institute a grant of up to \$600,000 over 3 years to establish the NCC.

NIFA published a request for grant applications for the establishment of two of the Regional Centers—one in the Southern Region and one in the Western Region—on May 18, 2015, which closed on June 29, 2015.<sup>2</sup> NIFA has awarded more than \$2 million in grants to establish these RCs. The University of Florida in Gainesville will establish the Southern Regional Center, with Oregon State University in Corvallis charged with establishing the Western Regional Center.

Additionally, on August 27, 2015, FDA published a request for grant applications for the establishment of the other two Regional Centers, one in the Northeast Region and one in the North Central Region.<sup>3</sup> This request is open through November 2, 2015, and eligible applicants can be found at the link provided.

*Question.* In your statement, you say that FDA plans to fund additional training programs through cooperative agreements. Please provide more detailed information.

*Answer.* FDA-funded cooperative agreements encompass a range of actions to support implementation of the FSMA rules.

- The agency has entered into a five-year cooperative agreement with the National Association of State Departments of Agriculture (NASDA) that brings together a range of state partners to collaboratively plan implementation of the forthcoming Produce Safety rule.

- Experts from FDA and NASDA are working together to develop a set of best practices for implementation of the produce rule. A coalition of states with strong interest in leading this implementation effort is actively participating in the development of these practices.

- NASDA will help facilitate industry training and will also play a role in the delivery of training to state regulators.

- To accommodate alternate approaches to FSMA readiness, the FDA plans to fund development of specific training programs through cooperative agreements. The agency's goal is to work with groups that understand the special needs of and have direct access to businesses that face unique circumstances and challenges in implementing FSMA. These training programs would include providing an awareness of the underlying reasons for the new standards and would ensure that training addresses the unique needs of the target audiences.

Specifically, cooperative agreements are planned to support curricula development and dissemination among two such communities: local food producers, including those engaged in direct marketing, and tribes.

- The agency plans to allocate fiscal year 2016 funds for the development of training curricula and delivery, in addition to education and outreach, with a focus on small and mid-size businesses involved in local food production, including those that engage in sustainable and organic farming. Eligible entities will include community-based organizations and other grassroots organizations that work directly with the intended audience.

- The FDA anticipates funding a similar cooperative agreement for the development of training curricula and dissemination in tribal communities. Tribal governments and community-based and/or non-governmental organizations will be among those eligible to receive the funding.

- The FDA will be involved in facilitating communications between the Alliances and the participants in the new cooperative agreements to maximize use of materials that are already developed, when appropriate.

*Question.* FDA officials have stated that if FDA doesn't get its full budget request, all of the increase provided will go toward the two rules just published, and produce safety will have to wait. Why shelve one very important item completely instead of taking a more pro-rata approach?

<sup>1</sup> <http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-15-003.html>

<sup>2</sup> [http://nifa.usda.gov/sites/default/files/rfa/FY%2015%20FSMA%20RFA\\_to%20post.pdf](http://nifa.usda.gov/sites/default/files/rfa/FY%2015%20FSMA%20RFA_to%20post.pdf)

<sup>3</sup> <http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-16-005.html>

*Answer.* The fiscal year 2016 President's Budget requested for each of its six proposed FSMA funding categories is the minimum amount FDA needs to effectively make progress on the critical implementation tasks in each category. All of the funding categories are vital to achieving FSMA's goals of a modern, preventive food safety system that protects consumers, strengthens public confidence, and reduces cost to industry from food safety problems. A significant shortfall of funding in these categories will unavoidably disrupt and delay FDA's plans for implementation of FSMA.

The urgency of receiving full funding in fiscal year 2016 is that it is the year that both preventive controls regulations are scheduled to become effective and, thus, the last year to make investments that are crucial to orderly, effective, and timely implementation. In FDA's own estimate of funding need, enactment of the President's request for a budget authority increase of \$109.5 million, for a total of \$1.3 billion in Budget Authority, and total Program Level of \$1.5 billion when accounting for all requested resources, would make it possible for FDA to move forward in 2016 toward successful implementation of FSMA.

If FDA were to receive less than full funding requested in the President's Budget for FSMA implementation in fiscal year 2016, FDA would focus on the highest priority activities. FDA's prioritization of activities aligns with the President's Budget policies related to FSMA. These priorities were decided with the full knowledge of the compliance implementation dates for the FSMA regulations identified.

FDA would prioritize its focus on the FDA and state inspection modernization, training and industry assistance investments needed to implement preventive controls in all food facilities effectively and efficiently.

FDA will make the best possible use of any available resources, but failing to make the proposed investments in any of these priority areas will force decisions to delay implementation of key elements of the new food safety system.

*Question.* Will your revised proposal for irrigation standards for fresh cured onions remain when the final rule is published?

*Answer.* As mentioned in the originally proposed produce safety rule (2013), we proposed to adopt an approach focusing on the likelihood of contamination of produce posed by the agricultural practices applied to the crop. We conducted a qualitative assessment of risk (QAR) of hazards related to produce production and harvesting. The draft QAR indicated that all produce commodities are potentially subject to similar microbiological hazard pathways: commodities can potentially become contaminated from, for example, direct exposure to contaminated water or soil amendments. Use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is otherwise relatively low. Therefore, we proposed to adopt a regulatory approach for minimizing the risks associated with those hazards and, as appropriate, provided flexibility for the use of alternative measures that would provide the same level of public health protection as the proposed standard.

We received many initial comments and questions on this approach and on the topic of agricultural water, some of which were submitted by the onion industry. We are considering these comments as we continue to develop our thinking surrounding food safety on the farm. With regard to your question on the proposal for irrigation standards and onions, we also heard many concerns regarding the treatment of onions under the rule during our listening sessions and meetings with growers. The proposed rule provides a staggered compliance approach which allows an additional two-year compliance period for farms to comply with certain agricultural water standards.

We have also evaluated the comments received to the docket for the Supplemental Notice and are carefully considering them in developing final requirements. Our goal is to determine an approach to agricultural water standards that will provide flexibility to allow the standards to be applicable to diverse irrigation and growing conditions, while still protecting public health.

*Question.* For irrigation water testing, the growers in my state were hopeful that FDA or USDA could look into ways to identify local, federally-approved, resources that could test irrigation waters strategically for an entire system, instead of requiring individual owners to test the waters of every ditch and pipe. Are you considering ideas such as this?

*Answer.* As outlined in our Supplemental Notice, we proposed to allow data sharing among farms if the farms are taking samples from the same water source and no there is no reasonably identifiable source of likely microbiological contamination between sampling sites and the points at which the farms draw their water. In fact, we encourage such sharing when appropriate. We included a proposed provision (§ 112.45(e)) that would explicitly allow data sharing under certain circumstances.

Under proposed provision § 112.45(e), we are proposing that a farm may meet the requirements related to agricultural water testing using the farm's own test results or data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent the farm's agricultural water source(s) and all other applicable requirements of part 112 are met. This provision would provide flexibility for a farm to determine the appropriate means by which to meet the proposed testing requirements in proposed § 1A112.45.

Under the supplemental proposed rule, farms using data collected by a third party or parties would still need to satisfy all applicable requirements of the proposed rule related to agricultural water testing. For example, the proposed rule includes requirements related to the timing of collection of samples, the number of samples collected, and specified analytical method to be used for testing, and recordkeeping.

We are currently evaluating the comments received on the topic and are carefully considering them in our efforts to determine an approach to agricultural water standards that will provide flexibility to allow the standards to be applicable to diverse irrigation and growing conditions, while still protecting public health.

#### QUESTIONS SUBMITTED BY SENATOR PATRICK LEAHY

First, I want to thank the Department and Deputy Commissioner for Foods and Veterinary Medicine Michael Taylor for continuing to engage with the state of Vermont and our farmers and specialty producers. I hope that the Deputy Commissioner's many visits to the state have helped you to develop the best program possible for the industry, farmers, and consumers.

But states and farmers are nervous, and rightfully so. There are serious price tags attached to these food safety rules, not only for the Federal Government, but also for the states, and for our farmers of all sizes who do not have the infrastructure in place to meet these new rules. I think we need to acknowledge that we cannot implement these rules without adequate funding. The FDA cannot implement FSMA on its own without involvement from the states, and we cannot ask our states to take on this burden on their own. Finally, we cannot expect farmers to make such monumental changes on their farms without technical and financial support.

#### STATE BUDGET CONCERNS

*Question.* Vermont is one of 25 states that do not have any authority or capacity, or framework for that matter, to regulate the produce industry. With no guarantee that there will be Federal funds to support them in this work, I hope you can understand the reluctance these states have to develop a new produce program ahead of that promise of support and any funding.

What assurances can you give to this Committee and states like Vermont that the FDA will prioritize this food safety work in your fiscal year 2017 budget request?

*Answer.* The continued implementation of FSMA remains a key priority for FDA and fiscal year 2017 will be an important year for FSMA implementation. In particular, FDA plans are currently focused on areas such as implementation of the Produce Safety rule and continuing to enhance our import safety systems.

FDA is currently working with the Administration to determine the appropriation level of food safety funding to include in the fiscal year 2017 President's Budget. We are looking forward to discussing our future budget needs in more detail when that determination is complete.

*Question.* What will you be able to do if we continue to face lean Federal budget years and we are not able to fully fund this work through the appropriations process?

*Answer.* In FDA's own estimate of funding need, enactment of the President's budget authority request for food safety of \$1.3 billion, an increase of \$109.5 million above fiscal year 2015 would make it possible for FDA to move forward in fiscal year 2016 toward successful implementation of FSMA. At this time, FDA would focus its efforts on the Preventive Controls rules which were finalized in September. We must continue our education and outreach efforts to ensure that industry is prepared to comply with these finalized rules. Beyond fiscal year 2016, without the additional funding requested in the President's Budget, FDA would need to reexamine FSMA implementation efforts.

The success of building a modernized food safety system depends on FDA and industry working together, as well as working with State and other regulatory and public health partners, after the final FSMA rules are issued. Full funding of the President's budget authority request is essential to maintaining momentum toward timely and comprehensive implementation of FSMA and avoiding the disruption and

loss of effectiveness that would result if FDA, the states and the industry are not adequately prepared to get implementation right. Without adequate funding to support this strategy, FDA will be unable to perform its job under FSMA, and the American people will not see the full public health benefits of the law.

FDA is firmly committed to implementing FSMA the right way from the start. This means investing in the food safety culture change that is happening within FDA, but it also means being faithful to the comprehensive, holistic vision of food safety modernization laid out in FSMA. Congress directed FDA to build a modern food safety system, addressing food safety challenges across the spectrum of farms, manufacturers, and transporters of food, both domestic and foreign. The pieces of this system are closely interconnected and FDA cannot credibly hold domestic producers to the new standards if we are not doing the same for importers and their foreign suppliers. Nor can FDA do the reverse, holding importers and foreign suppliers, but not domestic producers, to new requirements. FDA believes that if we do not implement the new FSMA-mandated food safety system in the comprehensive way Congress envisioned, from the start, we will fail to achieve the FSMA goals of food safety, strengthened consumer confidence, and a level playing field for U.S. producers.

*Question.* Are there ways to ease into the regulatory work the states will need to do until the FDA can provide them with the necessary amount of support?

*Answer.* The states will play a key role in gaining and maintaining compliance with the produce safety rule in the farming community, if funding permits. FDA is committed to working with our state partners to make this a reality. FDA is aware that there may be a variety of ways that states plan to assist and engage in facilitating and overseeing industry compliance with the produce regulation. These activities span from outreach and education to inspections on behalf of FDA or enforcement of comparable state requirements. FDA is also aware that the timeframe for states to engage in produce safety regulatory activities may vary widely. FDA is working with state representatives to develop implementation plans that provide for different collaboration models consistent with individual state's level of engagement in the produce safety regulatory paradigm. FDA is also exploring different mechanisms to oversee industry compliance in the event the state chooses to focus its activities solely on outreach and education or when additional time is needed by the state to establish an inspection program or to establish and enforce comparable state requirements.

#### SUPPORT FOR FARMERS

*Question.* In Vermont, where we are historically a dairy state, there are a lot of new diversified produce farms that are working on older dairy farms. That means they may not have metal processing equipment, or equipment they can sanitize, and there are exposed beams. Production agriculture most often takes place side-by-side with value added processing. For these farms, some of your rules will be a real challenge to meet as they look to modernize their operations. In a small state like Vermont, these requirements may cost upwards of hundreds of millions of dollars, funds these farmers simply don't have. I am struck that we do not have a "NRCS-like" agency at USDA or FDA to help the farmers to address food safety issues that are highlighted by these new rules. Running these farms out of business because of these costs cannot be the answer.

What partnerships can you develop with the U.S. Department of Agriculture (USDA) to help farmers make these infrastructure improvements?

*Answer.* FDA has been working with USDA for several years on all aspects of our produce safety regulatory program. For those small farmers that may need to add new food safety practices to their operations, FDA, in collaboration with USDA and other stakeholders, plans to offer guidance and other support to help them achieve compliance. More specifically, USDA staff worked with FDA to develop and review provisions of the produce safety regulation, and USDA staff are working with FDA and our state partners to develop post final rule implementation strategies and best practices that will enable state organizations to use their resources effectively. As mentioned above, FDA and USDA-NIFA are also co-funding one national and four regional coordinating centers for food safety training, which will focus on providing needed education and technical assistance to small and medium-sized farmers. FDA and USDA also jointly fund the Produce Safety Alliance, which is tasked with creating standardized curriculum covering FSMA requirements and good agricultural practices. The curriculum will include materials on understanding and performing a risk assessment for individual farms to consider in determining if infrastructure improvements may be needed. In addition, USDA administers a variety of grant,

loan and other financial assistance programs for which farmers may be eligible to apply.

*Question.* What new programs or authorities are needed to help our farms to modernize to comply with these new rules?

*Answer.* FDA is working at many levels to support programs aimed at assisting very small and small farmers to understand and comply with the produce safety rule. More specifically, FDA and USDA are funding educational opportunities to provide food safety training to produce farmers, such as training developed through the Produce Safety Alliance, so that they understand the basis of the requirements of the produce safety regulation and how to comply with the requirements. In addition, FDA has established a Technical Assistance Network to serve as a resource to respond consistently to questions from farmers and other stakeholders about interpretation and implementation of the produce safety regulation.<sup>1</sup> FDA is also working closely with our state partners to develop education and outreach programs that will provide important educational resources and tools to help farmers comply with the requirements.

*Question.* What should we tell a farmer in Vermont who cannot afford to make these improvements without Federal support?

*Answer.* It is FDA's intention to target our education efforts to the smaller businesses that may not be as familiar with our requirements, as well as some of the larger farms, so that they understand the regulations and have training and tools to comply with them.

Based on our outreach efforts and public comments, we proposed in September 2014 revisions to several key requirements of the original proposed rule on produce safety to be more flexible and less burdensome in key areas. For instance, we proposed a tiered and more targeted approach to water testing and revisions to the microbial standard for agricultural water used during growing produce (other than sprouts) that will be more flexible and less burdensome on farmers while still protective of public health. We removed the nine-month proposed minimum-time interval between the application of untreated biological soil amendments and harvesting until the agency collects and reviews further scientific evidence. We modified the definition of "farm" to help reduce the burden on a farm that packs or holds produce grown on another farm such that it would be subject to the produce safety rule and not also the preventive controls rule. The proposed rule also reduces the burden on small entities in part through the use of certain exemptions and limitations, and provides all farms flexibility for alternative practices to be used for certain requirements with adequate scientific support. In addition, States (including the state of Vermont, for example) could also submit a request for a variance for one or more requirements of the proposed rule. Finally, we proposed to provide farms that meet the definition of small and very small businesses an additional two and 3 years to comply with most provisions of the rule.

We recognize that it will take time and a concerted, community-wide effort for the wide range of farms to come into full compliance with the new requirements. FDA is committed to working with the produce community and with partners in the USDA, state and local agencies, and foreign governments to facilitate compliance through education, technical assistance and guidance.

At the Federal level, USDA has opportunities designed to assist farmers with developing and growing their businesses. These opportunities come in several forms—including education; outreach; and grant, loan and other financial assistance programs—all of which are designed to provide farmers with resources to meet their individual needs. Further, FDA established the Technical Assistance Network that we intend to link to external Technical Assistance Networks; these networks will collectively serve as a resource for anyone subject to the regulations who needs assistance with rule interpretation and specific technical or scientific questions. We are counting on USDA's Cooperative Extension personnel, among others, to play a key role in the external Technical Assistance Networks to help provide assistance to the industry.

(Additional information to USDA's various grant programs is available at: <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateA&navID=AMSGrants&leftNav=AMSGrants&page=AMSGrants&acct=AMSPW;http://www.grants.gov/search-grants.html?agencies%3DUSDA%7CDepartment%20of%20Agriculture>).

Again, FDA's ability to achieve our goal of successfully supporting farmers in compliance efforts is dependent on adequate funding.

<sup>1</sup>For more information, see <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

The FDA is working with the USDA to establish one national and four regional food safety training centers. I am concerned that limiting delivery of food safety training nationwide to just these 5 centers may not effectively reach the grass-roots level and the targeted, intended beneficiaries.

*Question.* Will the FDA also provide funding for on-the-ground food safety training to be delivered by university extension programs, non-governmental organizations, and associations representing farms and small food processors/wholesalers?

*Answer.* The Agency recently released a FSMA training strategy<sup>2</sup>, which outlines training options and delivery formats as well as introduces the partners in government, industry, and academia who are working with FDA on the development and delivery of training to the global community of food suppliers.

Industry training will be an important component of successful implementation of FSMA. The needs of small- and mid-sized farms and facilities are at the center of FSMA training development and will be met through multiple efforts:

- FDA has funded the creation of public-private Alliances (e.g., the Produce Safety Alliance, Food Safety Preventive Controls Alliance, and Sprout Safety Alliance) as a resource for industry and to facilitate widespread understand of the new requirements to support compliance.
- FDA is partnering with USDA's National Institute of Food and Agriculture (NIFA) to provide grants for food safety training, education, extension, outreach, and technical assistance to owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers. Community-based organizations (CBOs), non-governmental organizations. Cooperative extension programs are among the eligible entities to receive grant funding, and the requests for applications have specified that this program will provide significant opportunities for funding through subcontracts and for partnerships with eligible stakeholder groups who work directly with the target audiences
- Recognizing the great diversity among members of the food industry, FDA will be funding cooperative agreements that will develop training options for local food production systems and tribal operations.
- The agency is partnering with the National Association of State Departments of Agriculture (NASDA) to collaboratively plan implementation of the produce safety rule. NASDA will help facilitate industry training while also having a role in the delivery of training to state regulators.

It will take time and adequate resources to make these efforts work. FDA is committed to making sure that everyone in the food supply chain knows what training and education resources are available, and how to gain access to them.

#### RISK ASSESSMENTS FOR SOFT-RIPENING AND RAW MILK CHEESE

*Question.* I have heard from many Vermont cheese producers who are concerned about regulations the FDA may develop that will impact the production of soft-ripening or raw milk cheese. These concerns were highlighted in comments submitted to the FDA by Allison Hopper, CEO of Vermont Butter & Cheese Creamery, who is a producer of soft-ripened cheese, and a member and past president of the American Cheese Society, and Catherine Donnelly, PhD, a University of Vermont professor and expert on the microbiological safety of food who has developed an extensive knowledge concerning sources of and mitigation strategies for control of *Listeria* in cheese making facilities. I will also include these comments in this hearing record.

I hope these comments will help inform the Quantitative Risk Assessment the FDA is developing. Specifically, I would like to highlight a point that I hope the FDA will take to heart. Your risk assessments on soft-aged cheeses and raw milk cheeses include data relating to illegal, unlicensed producers. These producers are operating outside of the law, and will likely do so regardless of any regulatory changes. However, as Deputy Commissioner Taylor has seen first-hand, our small artisanal cheese makers in Vermont undertake extensive quality and safety programs to ensure their cheeses are safe. I fear that any regulatory change could have severe impacts on these Vermont cheese makers, even though they currently meet or exceed current regulations. These risk assessments are no doubt limited by a lack of information, but they could also be prejudiced by these cases of illegal or unlicensed producers.

What assurances can you give me, and to Vermont cheesemakers, that you will work to remove any data pertaining to these illegal or un-licensed producers from the final risk assessment so they do not create an unfounded bias against the careful work and processes done by our legal cheese producers?

<sup>2</sup> <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461513.htm>

*Answer.* FDA recognizes the broad diversity in cheese manufacturing operations and approaches and has been working with the American Cheese Society in particular to learn more about artisanal cheeses and measures that cheesemakers take to ensure their products are safe. In conjunction with the July 2015 release of the joint FDA/Health Canada risk assessment on *Listeria monocytogenes* in soft-ripened cheeses, we announced a request for comments that would assist our efforts to identify and evaluate measures that might minimize the impact of harmful bacteria in cheeses made from unpasteurized milk. The Agency is committed to working and sharing an open dialogue with the artisanal cheesemaking community as we work on these efforts.

The joint FDA/Health Canada risk assessment published in July 2015 was first released as a draft risk assessment in 2012, and public comments were solicited. The public comments were considered and incorporated in the final assessment, as appropriate. In conducting the risk assessment, FDA followed best practices established by national and international institutions, which include taking steps to reduce any possible bias that could be introduced by the data used, conducting a peer-review process, and providing an opportunity for public comment.

*Question.* I and others have worked hard to support and cultivate the artisanal cheese industry here in the United States. How are you working to harmonize our cheese regulations with the European Union so that we do not create trade barriers or risk American jobs?

*Answer.* FDA is not currently undertaking efforts to harmonize its cheese regulations with those of the European Union. As far as FDA knows, not harmonizing our cheese regulations with those of the European Union is not having a detrimental impact. That being said, FDA welcomes feedback on this issue and is committed to working and sharing an open dialogue with the artisanal cheesemaking community. The Agency remains dedicated to ensuring a safe and wholesome food supply using the latest science to protect human health, and promoting dialogue with industry, consumers and other interested parties.

#### SUBCOMMITTEE RECESS

Senator MORAN. Again, thank you for your testimony. Thank you for the way that you have answered questions today and have presented testimony. And please express my gratitude to the folks at FDA for the outreach that has occurred in the development of these orders of control.

With that, the subcommittee stands adjourned.

[Whereupon, at 3:26 p.m., Wednesday, September 16, the subcommittee was recessed, to reconvene subject to the call of the Chair.]



**AGRICULTURE, RURAL DEVELOPMENT, FOOD  
AND DRUG ADMINISTRATION AND RELATED  
AGENCIES APPROPRIATIONS FOR FISCAL  
YEAR 2016**

---

**WEDNESDAY, OCTOBER 21, 2015**

U.S. SENATE,  
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,  
*Washington, DC.*

The subcommittee met at 10:01 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Jerry Moran (chairman) presiding.

Present: Senators Moran, Blunt, Cochran, Daines, Merkley, Tester, and Udall.

A REVIEW OF RURAL DEVELOPMENT IN 21ST CENTURY AMERICA

STATEMENT OF HON. LISA MENSAH, UNDER SECRETARY FOR RURAL DEVELOPMENT

ACCOMPANIED BY:

TONY HERNANDEZ, ADMINISTRATOR, RURAL HOUSING SERVICE  
BRANDON MCBRIDE, ADMINISTRATOR, RURAL UTILITIES SERVICE  
SAMUEL RIKKERS, ACTING ADMINISTRATOR, RURAL BUSINESS-  
COOPERATIVE SERVICE

OPENING STATEMENT OF SENATOR JERRY MORAN

Senator MORAN. The subcommittee hearing will come to order. Good morning to those in front of us and to my colleague here at the dais.

Today, our hearing is one in a series in which we are focusing on the appropriations process and how it affects agencies under our jurisdiction. This one is attentive to Rural Development (RD) at the U.S. Department of Agriculture (USDA), and we are interested in the strategic investments that are being made and can be made on behalf of rural America and the people who live there.

Thank you, Under Secretary Mensah, for being here, and your three administrators. It is a pleasure to have you here, and we look forward to having a conversation with you about the nature of things that you are undertaking for the benefit of our country, but particularly the rural part of our country.

I particularly, again, would tell you in this public forum thank you very much for your visit to Kansas, and I am glad to hear you say that we treated you well. I would say that you are just being kind and polite, but I know that we did. I know my State.

Agriculture has been a bright spot and continues to be in our Nation's economy, 16 million jobs nationwide. I would say, Madam

Secretary, that one of the primary interests in my running for public office was a belief in rural America and desire to see that it prospers so that we have a chance to have our children and grandchildren raise their families in the places that we in rural America call home. It is something that we cherish, and it is something that we want to make certain is preserved and future generations have that option in their lives.

Rural Development is largely tasked with maintaining and improving that quality of life, and it can be providing loans for low-income families to own their first home, spurring economic development with grants to a small business, providing communities with financing to allow customers affordable utility rates.

Rural Development continues to serve a significant role, and we want to make certain that you have the necessary tools. I always indicate that a constituency of mine is taxpayers. We want to make certain that the money the taxpayers provide you is well-spent, and we are anxious to hear about that today.

#### PREPARED STATEMENT

Often, where I come from, economic development can be whether or not there is a grocery store in town. Many people in Washington, DC, do not have that experience, do not know how that could ever be an issue. But in many ways, they are some things that are very basic.

Many rural communities today are facing unique and ever-increasing issues related to urbanization and technology. Again, we want to hear what you have to say and work with you to see that good things happen.

#### PREPARED STATEMENT OF SENATOR JERRY MORAN

This hearing will come to order. Good morning. Today's hearing will focus on Rural Development at the Department of Agriculture and its strategic investments in rural America. Thank you Under Secretary Mensah, Administrator Hernandez, Administrator Rikkers, and Administrator McBride for being here today. Under Secretary Mensah, I enjoyed visiting with you recently in Kansas and hope you will return soon and often.

Agriculture remains one of the bright spots in our nation's economy, supporting more than 16 million jobs nationwide and forming the backbone of our rural communities. For those of us who grew up in rural areas, it is a lifestyle we cherish and hope to preserve for our children and future generations to come. Rural Development is largely tasked with maintaining and improving that quality of life. Whether it's providing loans for low-income families to own their first home, spurring economic development with grants to small businesses, or providing communities with financing to allow customers affordable utility rates,

Rural Development continues to serve a significant role in the nexus between need and opportunity.

In my home state of Kansas, we determine economic development by whether or not your town has a grocery store. Many issues facing rural communities are unique to those areas in an ever-increasing urbanized and technologically-advanced world. I look forward to discussing the Rural Development mission and other relevant topics with our witnesses today. We have a lot to cover this morning, so I will turn it over to Senator Merkley for any remarks he may wish to give.

Senator MORAN. We have a lot to cover, and I will turn to my ranking member, Senator Merkley.

## STATEMENT OF SENATOR JEFF MERKLEY

Senator MERKLEY. Thank you very much, Mr. Chair. Thank you for putting together this hearing. It is a pleasure to have all of our witnesses here today.

USDA Rural Development provides a remarkable set of opportunities to improve the quality of life in rural America. Very low and low-income families can receive the assistance they need to become first-time homeowners. Affordable multifamily housing and rental assistance is provided, particularly for very low-income and elderly and disabled rural residents.

Remote rural communities can receive the help needed to construct hospitals, schools, child and elderly daycare facilities, and obtain health and safety vehicles and equipment and other essential community facilities.

Other Rural Development programs include support for clean water and sanitary waste disposal projects and the expansion of high-speed rural broadband, which is critical for our rural communities.

Rural Development is sustaining America's longstanding commitment to ensure adequate and affordable electric service. In addition, Rural Development supports opportunities for the creation and expansion of rural businesses, increasing job growth and income generation.

Here in the Senate, we see these functions of USDA Rural Development as vital. There is strong support on this subcommittee for the work that you do. Of course, not everything always goes perfectly, and this hearing is an occasion for us to make inquiries but also to have you let us know of the difficulties that you are facing and the ways that program delivery could be improved to serve rural America.

We are also pleased that we will be having a second panel, which will provide perspectives on these issues from users, advocates, and interest groups. I want to particularly thank Mr. Tony Chrisman, who came here from Oregon to offer insights from his extensive experience developing and rehabilitating affordable housing for low-income families in Oregon.

So, again, Mr. Chairman, thank you for holding this hearing. I look forward to the testimony.

Senator MORAN. Senator Merkley, thank you very much.

Under Secretary Mensah, we are delighted to have you with us, and we look forward to your testimony now.

## SUMMARY STATEMENT OF HON. LISA MENSAH

Ms. MENSAH. Thank you so much, Chairman Moran, Ranking Member Merkley, and members of the subcommittee. Thank you for the opportunity to discuss the program successes and challenges of the Department of Agriculture's Rural Development mission area.

I am accompanied this morning by Mr. Brandon McBride, Mr. Sam Rikkers, and Mr. Tony Hernandez. They are the administrators for Rural Development's Utilities, Business, and Housing programs, respectively.

USDA Rural Development has a loan portfolio of more than \$210 billion. Thanks to your support, in fiscal year 2015, our staff provided funding of more than \$27.7 billion in rural areas throughout the United States and its territories.

Rural Development is the catalyst for rural renewal. The projects we support create jobs, attract private investment, stimulate entrepreneurship, offer new economic opportunities, and connect rural areas to the world. They ensure that our rural main streets and our rural small businesses matter.

Let me give you a few examples of what Rural Development funding does in a few States.

On my first trip to Kansas, you, Mr. Chairman, and I had the chance to meet USDA Rural Development business development grant recipients like Kansas Main Street. Our grants support locally grown business development in the downtown area of communities, which are so important to rural economies. In Kansas, I was also impressed to hear about the Kansas Fiber Network, a network of rural telephone companies, all rural utilities borrowers, that provide advanced broadband services essential to business growth and stronger rural economies.

This telephone company's network is dedicated to community outreach and business development, but it may not have been possible but for the low-interest loans we provide to rural telecommunications service providers. These affordable loan terms make financing possible for much-needed community investments.

In Montana, we have a very close partnership with private sector entities like community economic development organizations. In my visit to Big Sandy, Montana, which happens to be the hometown of Senator Tester, I had the chance to visit Big Sandy Activities, a center we financed there that helps developmentally disabled people build skills and allows them to live and work in the community. I also saw firsthand how our business and industry guaranteed loan program was used to purchase and restore the Grand Union Hotel, strengthening the tax base and bringing jobs to Fort Benton, Montana.

Rural Development support has enormous impact in small, rural towns. In my home State of Oregon, Imperial Stock Ranch in Wasco County is a family-owned and -operated business that supplied wool for Ralph Lauren designed sweaters. Supported by value-added producer grants, the Carver family has used these funds since 2008 to plan and for capital assistance.

When I asked Jeanne Carver what this program is doing, she explained that it is bringing life back to the textile industry and creating jobs in rural communities.

Our fundamental mission is to support thriving and self-sustaining and prosperous rural communities. The President's 2016 budget, which requests \$38.9 billion for Rural Development, proposes to continue this good work.

Every day, nearly 5,000 Rural Development professionals work to help rural businesses provide affordable rental housing and maintain and upgrade infrastructure investments. This work is important to the modernization of rural America and makes rural communities places where young people will want to stay, start families, build businesses, and create futures.

Let me say just a little bit more about our three areas. I want to begin with housing. This is a special point of pride, our housing programs.

Our 2016 rural housing budget of \$28.6 billion will continue to help people in rural America, particularly those in greatest need, put a roof over their head. The bulk of this budget, \$24 billion, supports private sector lenders in rural America and turns moderate-income rural Americans into homeowners.

Let me say another bit about Rural Utilities Service. Here for over 80 years, USDA has funded basic infrastructure services, which make a significant difference in the quality of life in rural America. These investments keep electricity reliable and affordable, deliver faster Internet service to rural families, and provide clean and safe water for rural communities.

Overcoming geographic and demographic challenges to offer access to robust broadband service is among the reasons that just 50 percent of those living in rural communities have high-speed Internet service. In our fiscal year 2016 budget, the new farm bill Broadband Program proposes \$44 million to fund broadband infrastructure, and the 2016 budget for the Electric Program requests \$6 billion to continue to provide reliable electric service to rural consumers while making improvements to increase efficiencies.

Let me say another word about our business and cooperative programs. These continue to bring investments and jobs to rural areas. The 2016 budget of just over \$1 billion will help continue rural renewal, benefiting not just our rural communities, but growing a stronger economy for the entire country through investment in rural businesses, energy, and entrepreneurial support.

Our 2016 budget requests \$75.7 million to provide loans and \$5 million in grants to rural small businesses, farmers, and ranchers to purchase renewable energy systems under our Rural Energy for America Program. Expanding investment in renewable energy projects improves the environment and helps create jobs.

This 2016 budget also offers funding to spur development with opportunities through the Value-Added Producer Grant Program, the Business and Industry loan program, and the Rural Business Development Grant Program.

Ungirding all these three programs is the investment we make in our people and our systems. The President's 2016 budget requests \$686 million for the salaries and expenses of USDA Rural Development. This is particularly important since Rural Development's loan portfolio has grown to over \$210 billion. It continues to grow each month, while staffing levels to manage this growth have not recovered from the declines of the past year.

Congress has provided significant resources to make a real impact in rural places. There is something extraordinary about rural America's ability to survive and thrive. Investments in rural America are investments in our country's future. With your continued support, we can leverage our resources to turn Rural Development's transactional work into transformational work.

I appreciate this opportunity to testify, and at this time, I am happy to answer your questions.

[The statement follows:]

## PREPARED STATEMENT OF HON. LISA MENSAH

Chairman Moran, Ranking Member Merkley and members of the committee, thank you for the opportunity to discuss the programs, successes and challenges of the Department of Agriculture's Rural Development mission area. I am accompanied this morning by Mr. Brandon McBride, Mr. Sam Rikkers, and Mr. Tony Hernandez, Administrators for the Rural Utilities Service (RUS), Rural Business-Cooperative Service (RBS) and the Rural Housing Service, respectively.

I am pleased to represent agency mission area with the primary responsibility of creating opportunities and improving the quality of life in rural areas. The investments we make in rural America contribute to rural growth, which is essential to national economic growth. Approximately 15 percent of the population of the United States is considered rural, while nearly 72 percent of our land mass is rural. Rural Development works on a daily basis to support the needs of that 15 percent—the 46 million American citizens that provide the food, fiber and fuel that the rest of the nation—and the world—depend upon.

USDA Rural Development has a loan portfolio of more than \$210 billion. In fiscal year 2015 our staff made loans, loan guarantees and grants of more than \$27.7 billion in rural areas throughout the United States and its territories. Because Congress has supported our field based delivery structure, Rural Development has staff in every state to make the loans and grants that help our rural communities become stronger and more vibrant.

Rural Development assistance includes direct and guaranteed loans, grants, and technical assistance. Rural Development's work is designed to maximize taxpayer dollars. Often our support is leveraged with private sector financing or is provided as a guarantee to private banks. Recipients contribute their own resources or obtain third-party financing, expanding the level of support we provide to rural communities. During this past year, the total Rural Development leverage—our use of non-Federal funds—was \$7.67 billion, or 118 percent of our \$6.5 billion goal.

Rural Development is the catalyst for rural renewal: the projects we support create jobs, attract private investment and stimulate entrepreneurship. Our investments build communities, offer new economic opportunities, and connect rural areas to the world. They ensure that our rural Main Streets matter and our rural small businesses matter.

On my first trip to Kansas, I had the opportunity to visit Emporia, and along with Senator Jerry Moran, recognize USDA Rural Business Development Grant recipients. These grants will help recipients like Kansas Main Street Inc. with small business development in the downtown area of communities. The work of Rural Development supports a shared American conviction that locally-grown businesses are important to rural economies and enhance the quality-of-life for rural residents.

In Kansas I was also impressed to hear about the Kansas Fiber Network, a network of rural telephone companies—all borrowers from our Rural Utilities Service Telecommunications program—which provides advanced broadband and telecommunications services—essential to business growth and stronger rural economies. This telephone company's network, which is dedicated to community outreach and business development, might not have been possible but for the types of low-interest loans USDA provides to rural telecommunications service providers. Rural Development's affordable loan terms make financing possible for much-needed community investments.

Every day, 4,600 Rural Development professionals work to help rural business, provide affordable rural housing, and maintain and upgrade infrastructure investments. This work is so important to the modernization of rural America; it connects citizens to broadband; it builds a cleaner future through renewable power and energy efficiency; it reduces child poverty by investing in businesses; it helps manage the growing healthcare needs of an aging population; and makes rural communities places where young people will want to stay, start families, build businesses and create futures.

When I was in North Dakota, Sen. Hoeven and I discussed how critical affordable, reliable infrastructure is to rural America. Economic development investments in infrastructure, business and housing are an important part of building strong, sustainable communities. Often these investments are simply not affordable. Loans and loan guarantees from Rural Development make these projects—which are so vital to rural growth—affordable to these communities.

Recovery Act funding delivered an unprecedented investment in rural areas. Broadband and water and waste infrastructure will continue to improve the quality of life in rural areas for generations to come. Our successful Recovery Act broadband projects mean that Reservation Telephone Cooperative in North Dakota can improve efficiency and security of oil production and pumping through electronic monitoring.

Baca Valley Telephone Company in New Mexico can now provide broadband across its 2,600 square mile service territory, serving some of the most remote farms and ranches in the U.S.

As a result of \$3 billion water and wastewater Recovery Act investments, 820 projects are providing cleaner, safer water to 2,883,673 rural residents. This funding provided awardees like Grady County Rural Water in Oklahoma, a new source of water to serve their community. Previously, the water used to serve the district was sourced through Ft. Cobb Lake and often suffered from high iron and manganese content. In addition, several of the district's customers did not have access to a public source of water, hauling water to their homes or businesses or relying on private wells. As a result of Recovery Act funding and RUS' water and wastewater programs, Grady County now has a new water supply to provide clean, affordable water to their customers.

Access to safe, clean drinking water is essential at any time, but especially during drought. Rural Development (RD) is actively working to assist eligible communities facing severe drought conditions. In the past 2 years, RUS has awarded 48 Emergency Community Water Assistance Grants (ECWAG) totaling \$18.6 million in California to assist rural communities suffering drought impacts. In fiscal year 14, RUS awarded 25 ECWAG grants totaling \$9,730,570 million to rural California communities. The Agency also provided assistance to the City of San Joaquin to upgrade their systems in response to the drought. In fiscal year 15, RUS awarded 23 ECWAG grants totaling \$8,870,944 for projects in the state. In addition the Agency awarded four Household Water Well Grants totaling \$730,461 to three California non-profits to provide low interest loans to rural residents for individual water wells, particularly in drought-impacted areas.

Rural Development also finances large, long-term loans to develop communities and grow businesses. We invest in smaller, specific projects targeted at the smallest producers. We provide financial support for underlying utility, housing and community facility needs of rural communities. These investments are the building blocks for economic development that is so critical to the future of rural areas.

Our Rural Business and Cooperatives Service (RBS), in partnership with other public and private sector stakeholders, promotes rural business and employment opportunities and supports key energy investments that grow rural Americans' ability to compete in the global economy.

One of the foundations of our work here in Rural Development is the close partnership we've developed with private sector entities like community and economic development organizations. Senator Tester and I visited several Rural Development projects, including Big Sandy Activities—a center that helps developmentally disabled people build skills to allow them to live and work in the community. I saw firsthand how our Business and Industry Guaranteed Loan program was used to purchase and restore the Grand Union Hotel in Fort Benton. This loan helped restore the Hotel, built in 1882, strengthening the tax base and bringing jobs to Fort Benton. Rural Development support has an enormous impact in this rural town.

The same B&I program provided DeVilbiss Healthcare, LLC with a loan to purchase equipment and machinery and to transfer manufacturing operations from China back to the United States. DeVilbiss manufactures and distributes respiratory medical devices and products such as nebulizers, oxygen concentrators, and continuous positive airway pressure equipment. The financial assistance preserves 92 jobs and creates 20 new jobs in rural Pennsylvania. These projects not only help rural businesses grow, but help reverse recent rural outmigration trends.

Loans and grants from our Rural Housing Service and Community Facilities Programs (RHS and CF) support rural residents and the communities in which they live. Congress has defined for us a powerful set of housing and community development programs to ensure that rural families can live in safe, affordable homes and thriving communities.

Rural housing programs anchor communities and play a key role in creating and sustaining wealth through home ownership. When a mobile home park in Shelburne, Vermont went up for sale, community leaders came together to ensure affordable housing would still exist downtown. Thanks to a \$1 million RHS loan, the Shelburne Vermont community now has the Wright House—one of five apartment buildings in Harrington Village, an affordable housing community that is home to over 36 senior citizens and persons with disabilities.

Our tribal investments support a wide range of needs in Native American areas. At the beginning of October, I was in North Dakota on the Spirit Lake Reservation to announce Rural Business Development Grants to create a business incubator in a renovated mall that would provide jobs and entrepreneurial opportunities. Rural Alaskan Village Grants are building water and waste systems, making communities safer and increasing the quality of life in remote Alaskan communities. High Energy

Cost Grants deliver cleaner and more cost effective energy sources across the country. Projects announced in September will benefit a number of Alaskan Natives and Native American areas, such as the project to install wind turbines in the St. Francis community of the Rosebud Sioux in South Dakota.

These are just a few of the many projects in which Rural Development is proud to invest. Our fundamental mission is to support thriving, self-sustaining and prosperous rural communities. Without RD funding, many rural communities could not make the investments to help them grow and prosper in the years ahead. Without these programs, rural communities would lack access to basic housing, safe water, broadband, and support for rural small business. Yet we know we have more to do.

We are committed to working with partners to best serve rural areas. We understand that solid public-private partnerships and well-placed intentional investments can—quite literally—mean life or death for some communities. Because of the funding you provide to us—\$38.3 billion in 2015—people who live in rural places today see historic opportunities in sectors such as local and regional food systems, emerging markets, the bio-economy, and manufacturing.

The President's 2016 budget, which requests \$38.9 billion for Rural Development—proposes to continue that work by giving priority to investment in rural businesses that want to take advantage of emerging markets as well as focus resources in areas of greatest need. Rural Business- Cooperative Service—A Force for Rural Jobs and Revitalization.

USDA's Rural Business-Cooperative Service (RBS) continues to bring investments and jobs to rural areas. The 2016 budget requests over \$1 billion to help continue this rural renewal—benefitting not just our rural communities, but growing a stronger economy for the entire country through investment in rural business, energy, and entrepreneurial support.

The 2016 budget requests \$75.7 million to provide loans and \$5 million in grants to rural small businesses, farmers and ranchers to purchase renewable energy systems and increase energy efficiency through the Rural Energy for America program. Expanding investment in renewable energy projects improves the environment and helps create jobs, ultimately offering opportunities to enhance prosperity in rural areas.

Today, we are using lessons learned from our lengthy experience in rural America to help communities capitalize on emerging opportunities in the 21st Century economy. Consider our work in the rapidly expanding area of local and regional food systems. USDA's "Know Your Farmer, Know Your Food" initiative provides tools and resources to farm and food businesses, including those run by women, people of color, and veterans as they tap into the growing market for local food. Rural Development is helping connect these rural businesses to new market opportunities with business planning assistance, infrastructure development and our boots on the ground to leverage resources and get the deals done for these businesses. In the last 3 years alone, we have supported over 600 local food businesses as they diversify and reach new markets.

For example, a Poplarville, Mississippi resident and veteran of the wars in Iraq and Afghanistan, launched a hydroponic agriculture operation. Funded in part by RBS, an "Armed to Farm" workshop helped this new farmer better manage the business side of his operation. After shadowing other agribusinesses, he says he now feels more confident about the future of his company, SmithPonics.

This 2016 budget offers funding to spur development of products and opportunities for rural business innovation with the Value Added Producer Grant Program, the Business and Industry loan program and the Rural Business Development Grant Program.

Throughout my travels to rural communities, it was clear that addressing the challenge of outmigration and giving our rural children opportunities to stay and use their skills to earn a living in their communities was extremely important to local community leaders, family members and businesses. I know this can be done. Imperial Stock Ranch in Wasco County, Oregon is a family-owned and operated business that supplied wool for Ralph Lauren-designed sweaters worn by United States athletes at the Sochi Winter Olympics. They also launched a "ranch-to-runway" line of clothing with award-winning fashion designer Anna Cohen. They did all of this nearly three thousand miles removed from the frenetic pace of New York City's fashion district. The Carvers have benefitted from USDA's Value-Added Producer Grant (VAPG) program since 2008, using funds for planning and capital assistance. Our VAPG program—one of nearly 50 programs and services administered by Rural Development—is breathing life back into the textile industry and creating jobs here in the United States.

RURAL HOUSING SERVICES—ANCHORING COMMUNITIES WITH HOMES AND ESSENTIAL FACILITIES

A special point of pride for Rural Development is our housing programs. Since 2009, Rural Development has helped more than 900,000 rural families buy, repair or refinance a home and provided funding for 3,000 multi-family housing developments. Access to safe, modest, affordable housing is vitally important to the health and growth of rural areas. Helping to make the American Dream a reality is a tremendous responsibility. I am delighted that through our housing programs are often stepping stones on the journey to homeownership which will help build wealth and security for rural families. We offer one of the best home mortgages in the United States and boast a low default rate.

The 2016 Rural Housing budget of \$28.6 billion will continue to help people in rural America, particularly those in greatest need, put a roof over their heads. The bulk of this budget—\$24 billion—supports private sector lenders in rural America by guaranteeing the mortgages they make to help moderate income rural Americans become homeowners. Another vital part of our housing program provides rental assistance to low-income people who live in USDA-financed multi-family housing. In fiscal year 2016, Rental Assistance of nearly \$1.2 billion will help create a sustainable program to offer rural residents—most of whom are seniors with fixed incomes—the security and peace of mind of a safe and affordable place to live. We have worked hard to address challenges of providing sustainable rental assistance to those who rely on this program, and I am optimistic that continued efforts and investment will lead to a stronger program to better serve rural residents.

In this, the 50th year of Rural Development's Mutual Self-Help Housing Program, we also completed 50,000 homes through partnerships and sweat equity. In fact, several Members of Congress and congressional staff participated in self-help builds this year to help us mark this important milestone.

Rural Development is committed to continually testing new ways to address housing needs in rural America. The USDA Energy Efficiency Manufactured Home Pilot Program was introduced this summer in New Hampshire and Vermont. A low-income home buyer interested in purchasing a high-performance modular home and placing it in a mobile home park would be eligible for a 30-year mortgage at a 3.25 percent interest rate. Very low-income home buyers may be eligible for an interest subsidy down to 1 percent. The mortgage is the first of its kind for residents of mobile home parks, where home buyers face high interest rates, short loan terms and high energy costs.

The Rural Housing Service (RHS) continues to make tremendous gains to its systems and processes—and recently took on a decade of needed upgrades. As of this spring, our guaranteed Single Family Housing loan program is now paperless. Not only are we saving 37,500 reams of paper every year, we've lowered postage costs, saved printer ink, and are moving loan guarantees out the door much more quickly and making our programs easier for our customers to use.

We are also in the process of modernizing the delivery of the Single Family Housing direct loan program through automation. Beginning fiscal year 2016, RHS will implement an automated underwriting system nationwide, permit third parties to submit applications electronically, and move from paper-based to electronic customer files. These improvements will provide underwriting consistency nationwide, additional security features, and the ability to seamlessly transfer work when states experience increases in applications.

The men and women of USDA take seriously the responsibility of supporting those who live and work in small towns and rural communities. They have worked hard to reduce backlogs, increase efficiencies and reduce program costs. These successes include the Single Family Housing Guaranteed Loan Program, which significantly decreased the amount of time staff spends processing a guaranteed loan request and save millions of dollars in cumulative operational and administrative cost each year. These time and cost-saving processes make it possible for government programs to continue manage a growing portfolio and meet mission goals with smaller operating budgets and reduced workforce.

From fiscal year 2012 to fiscal year 2014, Rural Development invested in 335 Public Private Partnership community infrastructure projects across rural America in 49 states. RHS leveraged over \$3.5 billion in community facilities direct loan funds from 2012 to 2014, with \$1.2 billion from institutional investors and the capital credit markets to strengthen investment in critical infrastructure projects, spurring economic growth and job creation, and increasing access to healthcare, education and other critical services. The 2016 budget request of \$2.3 billion for the Community Facilities (CF) program would enable 13.7 million residents to benefit from improved health, safety and educational facilities. Services such as those provided by

Pikeville Medical Center in Kentucky, which offers healthcare to patients from persistently poor areas, can grow. Pikeville Medical Center used the CF program to construct a new medical office building containing research facilities, outpatient surgery suites, endoscopy facilities, physical exam space, labs and lecture halls.

Building on this success, and working with others to understanding the needs of the region, Rural Development partnered with the University of Pikeville, the Appalachian Regional Commission, and the U.S. Economic Development Administration by providing a \$40 million Community Facilities loan for the construction of a health professions education building to provide instruction and demonstration for the new College of Optometry, School of Nursing, and other student support services. This funding enabled USDA to establish a Public-Private partnership for the new facility. This partnership resulted in a facility that added 75 jobs to the local economy and created a distributed community-based clinic model that added an additional 25 to 30 jobs in local clinics. In addition, the facility brought new services to the region, as previously there was no College of Optometry serving that state or many of its neighbors.

In communities like Pikeville, public private partnerships have bought together critical resources, innovative capacity, financial expertise, project development skills and technical assistance, to large complex community infrastructure projects at a time when RHS staff resources have been reduced. They have strengthened underwriting with another set of eyes, reducing RHS credit risk and providing a long-term partnership for servicing loans and communication with the borrower. Most importantly, these partnerships allow USDA to assist more rural communities, invest in vital community facilities, and help more rural residents.

In other rural areas, we are supporting organizations that are addressing more basic needs and on the front lines of the fight to alleviate poverty. Second Harvest of South Georgia is a non-profit that feeds hungry people in 30 Georgia counties and is the largest in Georgia outside of the Atlanta metro area. USDA provided funding through a \$5.2 million Community Facilities loan to build a distribution facility in Thomasville that produce up to 10,000 meals a day for South Georgia residents in need.

#### THE RURAL UTILITIES SERVICE—INVESTING IN INFRASTRUCTURE FOR A MODERN RURAL AMERICA

For over 80 years USDA has funded basic infrastructure services, which make a significant difference in the quality of life in rural America. Rural Utilities Service (RUS) investments keep electricity reliable and affordable and deliver faster Internet service to rural families and to businesses, allowing them to compete in the global economy. Our water and wastewater programs provide clean, safe water to help healthy rural communities grow and prosper.

We are proud of the work of RUS to deliver much needed broadband infrastructure in the past 5 years. Because of the Recovery Act Broadband Improvement Program, RUS was able to successfully invest nearly \$3 billion in 254 projects in 45 states and territories to deliver high speed Internet to rural areas unable to draw competitive for private service. As companies build out these services 260,000 rural households, 17,500 businesses and 1,900 schools, libraries and healthcare facilities have new service with potential for exponential growth in the future. Loans under this program have been extremely successful.

We know we still have work to do. Overcoming geographic and demographic challenges to offer access to robust broadband service is difficult and among the reasons that just 50 percent of those living in rural communities have high speed Internet service. The fiscal year 2016 budget request for the Farm Bill broadband program seeks \$44 million to fund broadband infrastructure in rural areas. RUS received 15 requests for \$118 million in funding for a \$55 million program, demonstrating the need to bring high-speed Internet to rural areas.

The White House in September released a report on ways to continue to bring broadband to unserved areas. We are beginning work on those important next steps of getting robust broadband service available to all who live in rural areas, not just the 50 percent who currently benefit from access to high-speed Internet.

We believe that all RUS programs that fund broadband will be an important resource in this effort, which is why the 2016 budget is requesting \$65 million, an increase of \$30.2 million over fiscal year 2015, for broadband access in rural communities that are least likely to have broadband infrastructure needed for economic development.

The 2016 budget request for the RUS electric programs is requesting \$6 billion to continue to provide reliable electric service to rural consumers.

INVESTING IN THE PEOPLE AND CORE SERVICES THAT MAKE RURAL DEVELOPMENT  
INVESTMENTS POSSIBLE

All of the good work of Rural Development is only possible because of the people who do this work. After years of retrenchment we are carefully rebuilding our staff and making sure they have the right tools to be strong partners in rural America. The President's 2016 budget requests \$686 million for the salaries and expenses of USDA Rural Development to support the delivery of the direct and guaranteed loans and grants, technical assistance and economic development strategies outlined above. In addition, this investment in our people will help us continue to provide quality service not just in our national office, but in the field, where staff know rural communities because they are part of those communities. New employee hires will fill mission-critical skill shortages resulting from a two-year hiring freeze. This is particularly important since Rural Development's loan portfolio has grown to more than \$210 billion, while staffing levels to manage this growth have not recovered from declines of the past few years. This level of funding also includes information technology investments to the Comprehensive Loan Program, which safeguards the portfolio from cyber threats and improves management capabilities.

Over the course of the last several years, we have chosen to be proactive in identifying and assisting areas of greatest need in rural America, rather than waiting for those places to find us. StrikeForce, Promise Zones, Stronger Economies Together and other initiatives are just a few of the many reasons that I am so fiercely proud of the 4,600 Rural Development professionals nationwide. Our Agency and its partners are willing to help us move assistance to the places that need it most.

Congress has provided significant resources to make a real impact in rural places. Yet the opportunities and the challenges of rural America make it clear to all of us that more needs to be done. I am deeply moved by seeing taxpayer dollars at work in rural communities. There is something extraordinary about rural America's ability to survive and thrive. It is a place where values count and where stewardship is a meaningful obligation. Working to address rural challenges is an amazing privilege.

In the time that I've been with USDA, I've witnessed rural resiliency on a very personal level. I watched the town of Floresville, Texas turn out in force to launch their improved water treatment system. I visited the Peoples Rural Telephone Cooperative in Jackson County, Kentucky which built a state-of-the-art, fiber-to-the-premise network that offers isolated rural residents the same economic, educational and social opportunities available to residents in urban areas. I toured a condiment manufacturer in Brundidge, Alabama that is expanding its business and market share with support from Rural Development. Each of these investments made in rural communities is an investment in our country's future.

I appreciate your continued interest and support of Rural Development programs. When countries cannot make rural infrastructure work, it impedes not only their rural places and people; it holds back the growth of the entire Nation. USDA Rural Development and our partners address the unique needs of communities often lacking large populations or other support mechanisms. Together, we can coordinate and leverage our resources to turn Rural Development's transactional work into transformational work.

I appreciate the opportunity to testify before the Senate Agriculture Appropriations Committee. At this time, I am happy to answer your questions.

Senator MORAN. Under Secretary, thank you very much.

We will turn to the gentleman from Montana and recognize him.

RURAL DEVELOPMENT VISIBILITY

Senator TESTER. Thank you, Mr. Chairman. Thank you for having this hearing, and thank you for your generosity in giving me a first crack at this, because I have another meeting.

Thank you all for being here. I appreciate it very, very much.

I am going to go a couple different directions here. I am also a product of rural America. You saw my hometown, Lisa, and it was good to have you there. You guys do a lot of good work.

You talked about the Rural Utilities Service (RUS). Quite frankly, I do not think we would have power to this day if it was not for RUS. The same thing could be said for telephone, and we will get to broadband in a minute.

But the question is now. I mean, that was in the days of my grandfather and father and mother and grandmother. So they knew it. They knew they would not have power unless we had the cooperative movement and government support. We would not have been able to cut the ribbon on that water processing plant in Big Sandy without Federal Government support.

Yet, when I go talk to my neighbors, I am not sure that they think the Federal Government had anything to do with any of these projects. What can be done about that? Quite frankly, we have to do something with the budget. We have to do things that are smart to move forward. I think pulling investment from rural America would be a mistake, but there are some who want to do that, and some of them are my neighbors who get full advantage of these programs.

So the question is, what can we do to educate people about these projects that would not be done, whether it is a water project in Big Sandy, whether it is Big Sandy activities, the second biggest employer in the town—by the way, the first biggest employer is the public schools, both government agencies, both government entities, in a sense—or whether it is revamping the private sector like the Grand Union Hotel that you talked about, which is a jewel and brings in a lot of business to that area. What can we do to inform people? What can you do to inform people?

Ms. MENSAH. Senator, I appreciate your passion about our almost invisibility in some ways, and I think there are a couple things we can do.

In part, we need our private partners to also explain our role in supporting them. So this is a partnership. When we come in and we do a renovation, we do it in partnership with our private partners. So we need some help from the people whose loans we guarantee to also say this message.

Senator TESTER. Okay.

Ms. MENSAH. And the other thing is the way we ourselves get out the word. One of the best things that I think you have done in this budget is to allow us to be a field-based agency. We are not invisible. We have staff in all of our 50 States that are the neighbors of these people. The more we can be the neighbors, I think we have a special advantage in a way other Federal agencies do not.

So I would say those two things.

Senator TESTER. Thank you. It is maybe not this way all over the country, but we have probably come off the best 6 years in agriculture we have ever had where I live. We have had incredibly good crops and high prices. That does not happen very often. Yet starting at about the mid-1980s, it has happened progressively along since the homestead days, but starting about the mid-1980s, we have seen a mass exodus off the land, an incredible mass exodus.

My farm, for example, we are 1,800 acres. People go, wow, that is big. No, that is about a third the size of the average farm in Montana. And, quite frankly, because of that consolidation both in the marketplace on inputs and the marketplace on where we sell our products because it is very limited, we have seen a lot of consolidation on the ground, a lot fewer farms, a lot less people, a lot bigger farms.

The chairman could probably say it in Kansas. I mean, rural America is de-populating in a big, big, big way. The rural population is declining across-the-board.

So when we talk about economic recovery, and we talk about your programs that are very important, we talk about the farm bill, we have to look and say, are we really doing economic development in rural America the best we can do? It could be argued, and it is argued by some with some merit, that these programs have all failed because the population is getting less, it is not getting more.

We are not seeing economic growth in rural America like we are in urban areas. We are not seeing people staying in rural America like they once did. As that swirl keeps happening, it gets worse. It does not get better, until we turn it around.

Now I will tell you that I appreciate the work you do, and I support your programs. And I think we need to be doing all we can do to empower you because I think you are the key, more than any other thing we do in rural America, whether it is in housing, broadband, whatever it might be, to bring it back.

#### BROADBAND ACCESS

But in Montana, and I would bet it is the same in eastern Oregon, and I would bet it is the same in Kansas, our broadband is not where it needs to be. I was going to say another word, but I am not. It is not where it needs to be. We have a lot of folks here being left out of the 21st century economy.

By the way, when you live in rural America, there are not a lot of customers, so broadband gives you that ability to get to those customers.

We just had Wheeler out, Chairman of the Federal Communications Commission (FCC), last week. Great guy, by the way.

Do you talk to him, Mr. McBride?

Mr. MCBRIDE. I have, yes.

Senator TESTER. Do you talk about what can be done in rural America, as far as utilizing your dollars, public-private partnerships, or however you want to do it, to maximize those dollars to get broadband to houses and businesses in rural America?

Mr. MCBRIDE. Yes, sir. Thank you for the question.

The President appointed a Broadband Opportunity Council earlier this year. What that council encouraged us to do more than anything else was to communicate more amongst agencies, know what other folks were working on in terms of expanding broadband access and how we can do that. That has helped us at RUS in terms of having regular weekly meetings with other agencies, including the FCC, and talking about what we can do to support the expansion of broadband access.

Senator TESTER. So what does that really mean? I mean, I got you. You are talking. And by the way, communication is important, and we need to break down the silos, and we need to go down that whole line. But what does that really mean as far as getting projects on the ground to get Montana wired up?

I would bet you a dollar to a doughnut, Chairman Moran can say the same thing about Kansas, and Heidi Heitkamp can say the same thing about North Dakota. So this isn't just Montana.

What are we doing? What are we actually doing to be more effective with the programs that we have, so that we know, when we fight like hell to get you extra dollars, that that money is actually getting to the ground and it is not getting ate up in administration, and it is actually doing what it needs to do to get these folks connected up?

Mr. MCBRIDE. Yes, sir. At the President's direction, what we have done is we have looked at each of our existing authorities and each of our programs.

Senator TESTER. How do you to determine need?

Mr. MCBRIDE. I am sorry?

Senator TESTER. How do you determine need?

Mr. MCBRIDE. Determine need?

Senator TESTER. How do you make that call, whether that money goes to north-central Montana, whether it goes to a place that is a little bit more populated, or whether it goes to an urban area?

Mr. MCBRIDE. Well, for our programs at RUS, there are loan applications. So we try to get the word out, go to conferences and visit with potential borrowers and the groups that are interested in expanding broadband. But then we work with them to see whether a loan application is possible and what would make sense for their business case.

Senator TESTER. I am not making a judgment here—and I am sorry for going way over time. I will wrap this up.

Do you feel that you are getting that information out so that your partners on the ground in remote frontier areas know their options?

Mr. MCBRIDE. Yes, sir. We can always do better, but we are doing the best that we can.

As the Under Secretary mentioned, we have a great field operation, and they do a lot of work in terms of letting people know about our programs. So we are doing the best that we can to spread that message.

But you are correct. Less than 50 percent of rural America has access to the same high-speed Internet.

Senator TESTER. And I will tell you, just in closing, it breaks my heart to see what is going on in rural America. It really does. I mean, in my hometown, we have lost both hardware stores. We have lost two of the three grocery stores.

We have even lost three of the five bars. That's how bad it's getting. I mean, now we have a crisis situation.

We have to be more effective. I am not going to be here for the second panel, but I really hope that the folks who are going to be on these panels address the kind of communication that you need to make sure we are doing it right from the top end, and, quite frankly, talk about the need that is out there, actually, if we met the need of your partners, if it would actually do any good at keeping people around or if this is just the trend and it is going to happen and we cannot do a damn thing about it.

I personally do not believe that. I do not think it is just on your shoulders, by the way. I think there are a lot of other things that we need to be doing about developing capitalism and the marketplace for the inputs and for our sales and all that kind of stuff, because it is a highly noncompetitive market in my opinion.

So thank you, Mr. Chairman. I appreciate the courtesy, and I apologize for taking too much time.

Senator MORAN. Thank you for joining us, Senator.

Senator Merkley.

#### PROGRAM DUPLICATION

Senator MERKLEY. Thank you very much, Mr. Chairman.

Thank you for your testimony.

Under Rural Development, there are approximately 50 programs. So if you were to identify two or three that need to be looked at very closely, as perhaps ones that are weakest or duplicates, what would you point to and say we should take a close look at this for potential consolidation? Or perhaps there is a more cost-effective way to achieve the same mission?

Ms. MENSAH. That is a hard question, making us choose between our children.

Senator MERKLEY. Yes, I know, choosing between your 50 children.

Ms. MENSAH. What I can say without—speaking impromptu here—is that there are 50 programs. Some are in statute that are very close to each other, so there are many specifics that tell us to work in particular areas, Alaska villages, colonias. I think there is a reason why we were asked to look specifically at those, even though it is broadly in the same area.

What I really think is that our three core areas, each have dominant players. There is no question that the Single-Family Housing Guarantee program dominates in our housing program. There is no question that the Business and Industry Guaranteed Loan Program dominates in our business program. There is no question in our Rural Utilities program, the size and scale of our electric programs and our new farm bill broadband.

What I have seen is that our administrators know how to get the most out of these programs. I don't feel that there is waste and costly duplication. What I feel is that every grant program that we have, and some of those are grant programs, there is a group of people who take so seriously how we get these dollars in rural America. So I would ask you not to look at the number of those programs, but look at their impact.

Some of our programs, even modest, like the self-help housing program of \$17 million, that is just such a critical program in the way it builds self-help housing. We have done our 50,000th house this year.

#### PARTNERSHIPS

Senator MERKLEY. Okay, so let's take that for a moment. Thank you very much for coming out to Oregon to visit a self-help housing program. Of course, it is wonderful that you come from Oregon. I was hearing the stories about Kansas and Montana and getting a little jealous, but I knew you would come to Oregon, and we are delighted you did.

But let's take that for example. That model of sweat equity, build your own house, low-cost loan, is very similar to the Habitat for Humanity model. Have we looked at whether that model makes sense to do independently or to do through subsidies to groups like

Habitat for Humanity? Is there a more cost-effective way to undertake it?

Ms. MENSAH. Well, I will ask Tony Hernandez. I know I will say that, actually, we have partnered with Habitat. I, in fact, saw a property this spring where we were direct partners with Habitat.

But, Mr. Hernandez, would you speak to our partnership with others?

Mr. HERNANDEZ. Thank you very much.

Senator, we are very excited to partner with lots of organizations. What we do best is that we are a mortgage company. We also provide technical assistance grants to help those nonprofits.

What we are doing with Habitat is trying to get them to use our product, which is the 502 direct loan, to help them build more homes. They are trying to become a mortgage company as well. We are a larger mortgage company. We can actually help them acquire more lots and use our product so they can build more homes.

So we are in the homeownership business, not just building and financing. What we are trying to do is partner with other groups, just like Habitat, across the country. We have met with the national Habitat organization and smaller groups to say, how can we help you do more if you use our product?

Senator MERKLEY. Thank you. I am going to cut you off there, because you are talking about the partnerships, which are wonderful.

I want to turn to another question, but I appreciate that.

#### RURAL ENERGY SAVING PROGRAM

The Rural Energy Savings Program is one that was authorized in the farm bill. Secretary Vilsack pledged to implement it. We understand that Rural Development, there is an existing program, energy efficiency and conservation loan program, which is similar to Rural Energy Savings Program in that it is basically low-cost loans to do energy-saving retrofits to buildings. However, it has not been taken up because interest rates are higher.

Has there been any progress that can be reported at this point in actually implementing the Rural Energy Savings Program?

Ms. MENSAH. Thank you, Senator.

I will say that you are correct that there is a similar program, but let me ask, since the Rural Energy Savings does work closely with our Rural Economic Development Loans and Grants (REDLG) program. Let me ask Acting Administrator Rikkers to tell you where we are in the process of implementing this.

Senator MERKLEY. Great.

Mr. RIKKERS. Senator Merkley, the RESPA (Rural Energy Savings Program Act) program, as it is referred to, we stand with you. You have been an advocate for cost-savings through energy efficiency both for small businesses and consumers that RESPA is targeted toward.

We are encouraged that the Senate mark on this year's appropriation bill provides funding for that RESPA program. With that funding, we believe that that will help clear a path and really help us continue to work with your staff to make and implement that program.

[The information follows:]

Rural Energy Savings Program Act (RESPA) is a voluntary program that will create jobs and lower energy bills for families, farms, and small businesses by promoting energy-saving improvements to homes and buildings in rural communities. The program will assist rural electric co-operatives in offering low-interest loans to their consumer-members for efficiency improvements, allowing repayment of the loan through savings on monthly electric bills. Individual co-ops or State-based groups of co-ops will apply to the Rural Utilities Service (RUS) within the USDA for loans to fund local energy efficiency programs. RUS loans to the co-op for efficiency programs will bear a zero percent interest rate. The co-op can re-lend to consumer-members for efficiency improvements at low-interest to defray the cost of administering the program.

Rural Development has developed a work plan and is currently assessing how to best implement the program in the loan portfolio of the Rural Economic Development Loan and Grant program.

Senator MERKLEY. Okay, I will look forward to future reports. Please keep me apprised.

My time is up. Thank you so much.

Senator MORAN. Senator Merkley, thank you.

#### RENTAL ASSISTANCE PROGRAM

Let me ask about housing, Mr. Hernandez or Madam Secretary. Over the last 3 years, appropriations for rural rental assistance have grown by \$336 million. Yet we have indications that the amount requested for rental assistance renewals for fiscal year 2016 will not be adequate.

We have worried about that. In fact, our appropriation bill language criticizes the administration, the program, and the ability of Rural Housing Services to provide accurate information on the amount needed to renew those existing rental assistance agreements.

Can you provide detailed information on the amount necessary to renew all the expiring rental assistance agreements for fiscal year 2016?

Ms. MENSAH. Thank you, Senator, for the question about rental assistance. As you know, this drives our ability to be in the affordable housing business in rural America, 14,000 properties, and rental assistance is crucial to it.

There is no question financing this program is a challenge for us. We continue to be in conversation with you because it is a challenge. Our estimates are made 2 years in advance. And yes, they are often off.

So we acknowledge this challenge. We acknowledge that, yes, we will likely need more than we had estimated. I do not have a precise number for you today.

Senator MORAN. We, certainly, would like that information. Obviously, the appropriation bill requires that information be provided. You need it to manage the program. We need it to make certain that we do our job in a fiscally responsible way, so there are no surprises.

With a fixed amount of money that we have to spend within this budget, that number helps determine what other programs within USDA, including Rural Development, might receive. That requires us to have the best information possible to make those decisions.

So I reiterate that request, and we look forward to having a conversation with you to get those numbers.

Ms. MENSAH. Thank you. I look forward to that as well. We take it seriously.

[The information follows:]

When formulating its budget request, RHS uses the best estimates of local tax, utilities, and other operating expenses. However, these items may change and cause fluctuations above the estimate. To help moderate the impact of cost fluctuations that the agency can account for, RHS implemented an updated method for obligating rental assistance (RA) in October 2015. This tool provides more accurate estimates of future property-level funding needs. It also processes rental assistance contract renewals more quickly and efficiently. The updated RA obligation tool estimates RA needs on a per property basis, with the objective of improving accuracy by using more timely data and reducing the incidence of second renewals. The obligation tool provides as near-real time data as possible, and the built-in inflation factor adjusts for the time lag between budget development and receipt of the appropriation. The revised estimate for fiscal year 2016 is \$1,389,695,000, which is \$217,795,000 above the fiscal year 2016 President's budget request. The revised estimate assumes that the re-renewal prohibition carried in the fiscal year 2015 law will not be in the fiscal year 2016 law, including for the units with contracts renewed during the current continuing resolution which carries the fiscal year 2015 prohibition.

#### UNIVERSAL SERVICE FUND

Senator MORAN. Let me ask, this could be for you Secretary Mensah or Administrator McBride, the issues related to RUS and the FCC, it was raised a bit by the Senator from Montana. But it seems to me that we have set the stage in which the FCC has made decisions related to revenues that are going to be received that then affect the ability to repay loans.

So I have been worried for a long time, going back to the original order of the FCC particularly related to the Universal Service Fund, whether or not companies across Kansas and around the country will have the necessary revenues, first of all, to provide the service, but secondly, in the absence of adequate compensation for the Universal Service Fund, the ability to repay RUS.

You indicated conversations have taken place. I have tried to get Rural Development and the FCC chairman in the same room to have these conversations. It seems to me that there was an unwillingness to have that occur.

So what I am looking for is I guess the degree of coordination that is taking place. I heard you indicate to Senator Tester that meetings occur, but can you assure me in pretty definite terms about the assistance that RUS is making known, the problems and challenges that will arise to your borrowers should orders affecting the Universal Service Fund continue down the path that they have been on.

Mr. McBride or Secretary.

Ms. MENSAH. I think I will ask Administrator McBride to speak to this issue of coordination.

And you have asked for an assurance? I can tell you we will assure you that we will be in dialogue with our Federal partners on this.

Senator MORAN. In that regard, how serious is the issue? Am I raising something that is relevant?

Mr. McBRIDE. Any time that you are talking about something that will impact one of our borrowers, I have concerns, because we

want to make sure that our portfolio is strong, and we believe that it is.

In terms of what is happening with FCC, we do communicate with them regularly. As they develop their proposals, we provide some feedback. But they are a regulatory agency, so there is a little bit of separation there. But we do try to discuss the potential impacts of their rulemaking.

Senator MORAN. They are a regulatory agency, and they are an independent agency, but you are part of an administration. What I am looking for is that there is an assurance that at a higher level within the administration that the position that Rural Utility Services is in and will be in as a result of decisions at the FCC related to Universal Service Fund is being communicated to the FCC.

I guess I am also interested in—you tell me that you communicate with them, what do they say? Have you seen any evidence that they are doing anything different, as a result of you raising these issues?

Mr. MCBRIDE. Yes, sir. They have heard our concerns, and I know that they have tried to take that into consideration. We have communicated that at a high level with them.

Senator MORAN. Let me go at this one more time. Fortunately, as the chair, I get to have as many rounds as I like, so I will see if I can ask this question perhaps for the last time on this topic. But tell me what your concerns are. How dramatic of a consequence could changing the Universal Service Fund be to the ability of your borrowers to pay back their loans they have borrowed? And what is the contingent or possible liabilities that will accrue to your agency as a result of FCC orders?

Mr. MCBRIDE. I do not have the answer to your second question, because I do not know exactly how they will make final changes to the Universal Service Fund (USF). I know that they are aware that we are concerned about their modeling and how that might impact our program. We have shared that information with them and had those conversations with them.

Senator MORAN. In another round, I would like to explore further why perhaps rural telephone companies and others, potential borrowers, are not seeking loans from RUS. My guess is that there is a causal relationship because we do not know what the FCC is going to do in regard to the Universal Service Fund, so there is not only the fear of, "Can I repay my loan?" but there is also the fear that I should not take out a loan. The consequence there is that fewer Americans in rural America will be served by broadband.

Mr. MCBRIDE. You are correct that there were some concerns in recent years. Actually, this year, we did see a slight increase in terms of the loan dollars that we were able to put out from our traditional infrastructure program. We also saw an increase in applications for our farm bill broadband loan program. So there is an increase in interest in our programs.

Senator MORAN. I look forward to exploring that. Thank you, Mr. McBride.

The Senator from Montana, Senator Daines.

Senator DAINES. Thank you, Mr. Chairman.

## BROADBAND AND UNDERSERVED COMMUNITIES

I spent decades in the private sector before coming to Washington, DC. I was, for 12 years, part of a cloud computing company we started up in Boozman, Montana. We took the company public. Oracle acquired us a couple years ago.

In fact, if I were to ask you where Oracle was going to put their North America cloud command operation center for the entire Oracle cloud, if I said, is it going to be in Silicon Valley, Boston, New York, perhaps even Tel Aviv or Singapore, if I told you it was the Boozman, Montana, it wouldn't have been your first guess, anyway.

I think this is showing what is going on in technology today, where technology has removed geography as a constraint and this nexus of a quality of life of rural America that we have, where the millennials say, "I want to have my cake and eat it, too. I don't want to have to sit in traffic for 2 hours. I want to be able to get to a trout fishing stream, get to the mountains, and so forth. But I want a world-class career, best in class, that relates to my business experience, too." We have that now, thanks to technology.

So I've lived it. I've breathed it. I'm passionate about ensuring that we provide connectivity here for all of America, including rural America.

That also translates to our ag communities, where our farmers and ranchers are now high-tech operators, in terms of what they do. It is amazing what is going on there. Certainly, in agriculture, we improve productivity and we not only feed our country, we feed the world.

So a question for Under Secretary Mensah. In your testimony, you highlight the need for more work to be done in expanding rural access to broadband and that just 50 percent of those living in rural communities have high-speed Internet service.

Despite this fact, the administration's Broadband Opportunity Council recently released a report on increasing broadband employment and directed RUS to make funding available in areas that already have a broadband provider.

Many communities in Montana, and I know I can speak—Senator Tester was just here earlier and made his comments from a Montanan's perspective.

By the way, we had Chairman Wheeler, Senator Tester and I did, last week in Montana. It was great to have him there to see what is going on in rural America.

But many Montanans do not have access to broadband, not even one provider, let alone thinking about having two. We should be focusing dollars, I think, on unserved communities, not just improving speeds for those who already have connectivity.

So the question is, how is RUS going to avoid duplicative investment and make sure that funding is given to those who need it, who virtually have no connectivity at the moment?

Ms. MENSAH. Thank you, Senator, for raising this issue. Thank you. It is, certainly, our intention to serve rural America with broadband services and to reach those areas which are beyond the last mile. So I want to share your seriousness about this.

Let me ask, though, Administrator McBride to explain what it is like within the Rural Broadband program and RUS, and explain

how we look at applications in our already-oversubscribed farm bill Broadband Program, so that we do not have a duplicative situation.

MR. McBRIDE. Thank you for the question, Senator.

What the Broadband Opportunity Council overall was trying to look at was that there are some differences between broadband availability in rural America versus urban, in terms of high-speed Internet. So that was one of the issues that the council looked at.

In terms of how we administer our programs at RUS, in the 2014 farm bill, Congress included language directing us to require at least 15 percent of a potential application area be unserved. So we have direction from Congress to include that percentage of unserved residents.

And also the farm bill sets the standard in terms of how many incumbent providers can already be there. So if there are already three providers in a proposed service territory, that application would be ineligible.

#### BROADBAND SERVICE IN TRIBAL AREAS

Senator DAINES. Let me ask a follow-up on that, pivoting over to our tribal lands. Montana is home to 12 federally recognized tribes, plus one State-recognized tribe, the Little Shell. Thanks to the dedication of Montana companies, like Triangle Communications, residents of the Rocky Boy and the Fort Belknap Indian reservations have access to broadband for the very first time.

However, the broadband access on tribal lands continues to be an issue. In fact, high-speed broadband on most tribal lands in Montana is virtually nonexistent.

Since 2009, USDA has awarded nearly \$20 million in funding to provide broadband service in tribal areas. So the question is, what does RUS plan to do going forward to connect tribal communities?

MR. McBRIDE. Thank you for the question, Senator.

We are trying to expand our outreach to tribal areas and help them understand the programs that are available to them and potential applications.

Earlier this year, we funded our first substantially underserved tribal area telecom application in New Mexico. That was a great project there that brought fiber to the homes in that area. So we are, certainly, open to this and would be happy to work with your constituents on this.

Senator DAINES. I am out of time, but the last comment, I think these investments in broadband infrastructure are really investments in innovation. This is really an opportunity what we are seeing around our country that we can lead globally here.

When I was running businesses there in Boozman, Montana, I had an office in Tokyo and one in Sydney, but I could do it right there from Montana. This is really the wave of the future for our country. Thank you.

Senator MORAN. Senator Daines, thank you very much.

The Senator from Mississippi, Mr. Chairman, welcome.

#### STATEMENT BY SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, thank you. I am pleased to join you in reviewing what the status of these programs are that are administered by this panel of witnesses.

Thank you for the good work that you do and the outreach that you undertake to help acquaint organizations out there in the small towns and communities of rural America that there are Federal programs that are designed to make available fundamental ways of enjoying living out in the country, as they say, and yet having some of the modern conveniences that so many of us take for granted. So thank you for being here today and helping us review and implement ways that this subcommittee can be helpful through either legislative language suggested for adoption by Congress or regulatory action that you would like to modify.

We want to work with you and be helpful to you.

We are from the government. We are here to help you.

Senator MORAN. Mr. Chairman, thank you. Thanks for joining us.

The Senator from Missouri, Senator Blunt.

#### BROADBAND ACCESS

Senator BLUNT. One other topic on the connectedness issue, which I think we all understand is really important that we get this done so that everybody does have capacity to compete and to offer products and to communicate.

Mr. McBride, you mentioned a couple times unserved and underserved, and I wondered what programs you have that address both of those things. Frankly, several of us are on the Commerce Committee as well, and I am much more interested in assisting unserved areas than I am assisting a second competitor where there is already somebody there that might meet some definition of underserved.

So do you want to talk about that a little bit, the difference in unserved and underserved, and what programs you might have, what areas, in both those categories?

Mr. MCBRIDE. Yes, sir. Thank you for the question.

We have four primary programs where we fund the expansion of broadband access. The first is our traditional infrastructure loan program, which is targeted to communities of under 5,000. We have a farm bill broadband loan program, which the population goes up to 20,000.

Then we have two grant programs. One is the distance-learning and telemedicine program, which helps improve health care access and educational opportunities. That is a grant program.

The program that we have that actually targets unserved areas is called Community Connect. The subcommittee gives us around \$10 million to \$15 million a year, I believe, to make small grant awards to communities that do not have existing broadband service. That is our primary tool in terms of getting to communities that do not have access.

Senator BLUNT. Are the other three available to both underserved as well as unserved communities?

Mr. MCBRIDE. Yes, sir.

Senator BLUNT. Then you look at those applications and decide where you are gaining the most new service?

Mr. MCBRIDE. Yes, sir.

In terms of the distance-learning and telemedicine, and the farm bill loan program, both of those programs are oversubscribed, so

the competition is quite difficult for both. So certainly for the loan program, we are looking at areas where there is not much service or it needs to be improved.

Senator BLUNT. Thank you, Mr. Chairman.

Senator MORAN. Thank you, Senator Blunt.

We are going to do another round of questioning. I am going to try to limit mine to perhaps one area, and it is back to you, Mr. McBride.

Mr. Rikkens, do you feel left out? Or pleased?

Mr. RIKKERS. Happy to be here, sir.

Senator MORAN. All right.

#### BROADBAND OPPORTUNITY COUNCIL RECOMMENDATIONS

Senator Daines talked about this, Senator Blunt talked about this, underserved and no service. We have seen examples of that in our State. I noticed that in the development of your rules, you are headed toward the direction of not making loans when there is a loan to another company who already has and is providing service in the area, another RUS loan recipient.

Mr. MCBRIDE. Yes, sir.

Senator MORAN. I did not say that very well.

Mr. MCBRIDE. I understood.

Senator MORAN. Thank you for understanding. You have made the decision that you are not going to make loans to companies who want to provide service to a place that there is already a company providing service with an RUS loan. Is that accurate?

Mr. MCBRIDE. Yes, sir.

Senator MORAN. And the part that caught my attention was the Broadband Opportunity Council's recent report. It seems to go the other direction. It is an August report that says, broadband loan eligibility should be expanded to different providers "even though an incumbent exists."

How do you square what RUS's policy is versus what the broader group of people is saying is the goal?

Mr. MCBRIDE. Certainly, with the Broadband Opportunity Council, the good thing about the council and its recommendations is that we were looking at all of our suite of programs to see what we could do to support broadband access. The council's actions would not require additional funding or additional legislation. It was just simply to look at our programs to see what we could possibly do.

In terms of the issue that you raised, of course, we will have to follow what is in statute and what Congress has directed us to do, in terms of looking at potential applicants where there are already service providers. So that will be our lead focus.

Senator MORAN. Tell me once again what you understand Congress' direction to be in that regard.

Mr. MCBRIDE. Well, in terms of the farm bill loan program, if there are three existing service providers, then an application to serve that service territory would be ineligible.

Senator MORAN. Okay. When you make a determination about an RUS loan to provide broadband services, the subsidy that is provided by RUS, is it what is designed to be the sufficient amount of additional revenue to make the service available to make it

work? The question I have is, do you bring in other territories that already have incumbent providers, a larger community, for example, and allow a loan recipient—duplicate service is not the right phrase, but add additional service when there is already service being provided as part of the revenue source, so that areas that have no service get that additional revenue?

I will try one more time. My question is this, is the subsidy sufficient to make this work, or do you need to have larger population areas within that territory to further subsidize the ability for that carrier to provide broadband?

Mr. McBRIDE. The three basic things that we would look at for new application are: Is the population of the area that they want to serve under 20,000? Did they include at least 15 percent of an unserved area in their application? And then, how will their finances work?

So we want to look at all those things to see what they do. Some of the applications that we received in the most recent round, they were proposing to serve up to 50 percent unserved. So we want to make sure that there are fewer than three existing service providers, and that they meet that target in terms of unserved population.

Senator MORAN. Fifteen percent of the proposed area of service is the requirement for the loan? Your application is based upon an area that has no service, that has to equal at least 15 percent of what they are applying to serve? Is that what you are telling me?

Mr. McBRIDE. Yes.

Senator MORAN. The other 85 percent could have an additional provider already providing the service.

Mr. McBRIDE. Yes.

Senator MORAN. Okay.

Mr. McBRIDE. As long as they do not have more than three.

Senator MORAN. And the revenue that is generated from that 85 percent may be taken into account to determine your final criteria of whether or not this is fiscally, financially possible.

Mr. McBRIDE. Yes. We have to make sure that any loan that we make, that they will be able to repay us and be successful.

Senator MORAN. Okay. Thank you.

Senator Merkley.

Senator MERKLEY. Thank you, Mr. Chairman.

#### RENTAL ASSISTANCE 2015 SHORTFALL

I want to go to rental assistance in more detail. The chairman asked about the shortfall, and the numbers that we have been provided for the shortfall for fiscal year 2015 was, very precisely, we're talking basically \$101.5 million, precisely, is the number provided by your department.

In the second panel, Tony Chrisman is going to present his story, which is typical of what has happened with that fiscal year 2015 shortfall, which is that the individuals who are operating multifamily projects, who own these projects, they are paid for each unit. Each unit, the family pays 30 percent of their income and then the balance is paid through this rental assistance program.

But in August, mid-August, the money ran out. So the folks who have these multifamily projects stopped receiving payments.

For example, for Mr. Chrisman, the total amount of rental assistance not paid to date is \$365,000. That is that share of that \$101.5 million shortfall.

We provided authority for those shortfalls in fiscal year 2015 to be filled back in, but the owners have not received any notice that they are going to be compensated for that shortfall. Are you planning to fill in the shortfall in 2015? Or are we going to leave these owners across America just hanging out there suffering this loss?

Ms. MENSAH. Thank you, Senator Merkley. That is, certainly, not our intention to leave owners hanging.

I am going to ask Administrator Hernandez to speak to your specific question about how we want to catch up the shortfall that we had in fiscal year 2015 as we head into fiscal year 2016.

We are thankful that we were able to limp across the line into September, into our new fiscal year, and we do want to bring that whole again.

Mr. HERNANDEZ. Great. Thank you very much.

Senator, our goal is to try to help as many of those property owners as we can. First of all, we are going to use the allocation that you have given us for appropriation this year for the continuing resolution (CR). We will fund those property owners who have run out of money and they are into the new fiscal year.

Senator MERKLEY. So be specific. Are we going to backfill the missing payments from fiscal year 2015, the August and September payments that we failed to pay?

Mr. HERNANDEZ. We are trying to figure out how we can do that, sir. Right now, we cannot use the CR money to do that by statute, so we are trying to figure out—

Senator MERKLEY. My understanding is that we did enable that to be done, but that there is reticence to do so. Is there a legal question? This has not come back to my attention. This is an issue we have been raising continuously. Can you please get us exact details on how that is the case? That was fully the intention that this was to be able to be backfilled.

Mr. HERNANDEZ. I will find out how we can do that.

[The information follows:]

The USDA is committed to delivering a sustainable rental assistance program and has made significant progress in addressing the challenges in managing the statutory and funding cycles of this important program. The fiscal year 2015 appropriations law prohibited a property from receiving a second renewal of fiscal year 2015 Rental Assistance (RA) agreement funding within a 12-month period. Because of this, the agency was prohibited from providing a second renewal in fiscal year 2015 to 44 properties. Rural Development (RD) advised borrowers about steps that could be taken in order to leave operating funds in project accounts to pay project expenses, to the extent possible. The prohibition on second renewals was lifted by the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2016 (Continuing Resolution) for properties that were renewed in fiscal year 2015. However, there is no additional language in the Continuing Resolution that allows USDA to reimburse the properties that did not receive the needed RA funding in fiscal year 2015. Funding made available during the Continuing Resolution (CR) period allowed USDA to renew all the RA Agreements that needed a renewal as of October 1, 2015, under the same terms and conditions as previously authorized in fiscal year 2015 and it also included being able to renew the contracts for those properties that were prohibited from a second renewal in 2015. However, that prohibition remains in place for the 2016 contracts written under the CR authority per the same terms and conditions requirement.

Senator MERKLEY. Okay. Because otherwise, you have all these owners who we made a contract with, we left them hanging. That can bankrupt a company very, very, very quickly.

Furthermore, it sets up a real dilemma, because when someone leaves one of these units, the owner is required to take the family on the list who has the greatest need, which means their 30 percent of their personal income is going to be very little. If they're facing a situation where they are supposed to take a family who can pay very little rent, but then the U.S. Government is going to fail at the end of the year to complete their contracts, that is unacceptable, isn't it?

Mr. HERNANDEZ. Sir, we are working with your team to try to make sure we have more predictability, increased accuracy in the way we do the funding, to try to understand the costs of the buildings. That is why we have implemented new tools to have better accuracy in forecasting what it will cost.

Senator MERKLEY. This is what I want to know. I want you to come back to us, and we will work together. This is rural affordable housing across America. We are talking about 260,000 units, 14,000 projects, which got shortchanged.

I don't think it is the intention of any of us that we should not fulfill the vision that we laid out.

This is going to have huge repercussions for future willingness for developers and owners to participate in this program. Let's get this fixed.

Madam Secretary, you didn't have a number for fiscal year 2016, but the numbers that we have been provided is that we are \$120 million short by best estimates on top of the \$101.5 million for fiscal year 2015. That is a huge issue.

So if we are going to be running out again this coming August, we have to fix this. We need you all to come to us with a proposal so we can have this subcommittee really chew on it and say, okay, well, my understanding is it was fixed in the continuing resolution so it could be backfilled, and then for the start of fiscal year 2016, the authority was to be able to kind of forward load the funds. So we still had a problem, but at least we had fixed it for our owners for fiscal year 2015.

I am hearing it has not been fixed. When I hear that there isn't a precise number for fiscal year 2016, I am afraid we are going to have this crisis again at the end of this year.

Now that I have eaten up all my time, I just want to say, let's get to the bottom of this. Propose to us plans A, B, and C, and let's figure out how to resolve this.

Mr. HERNANDEZ. I look forward to the partnership, sir.

Senator MERKLEY. Thank you.

Senator MORAN. Senator Merkley describes my understanding of the situation as well, that this was fixed, the backfill should occur. If there is a problem within the agency, we need to know that. My understanding is that your general counsel is trying to figure out how to do it. We believe we gave you the authority to do it.

That does not solve the problem at the end of the next fiscal year, but it solves the problem at the moment. And it reduces exacerbating the circumstances we face in the future.

Senator Blunt.

Senator BLUNT. Secretary Mensah, several questions on what the FCC might do that impacts what your agency is trying to do.

#### EPA RULES

On other rules and regulations, the Environmental Protection Agency (EPA) has a couple rules now that have real impact in rural America, the power rule, I think about 75 percent of the landmass of the country is served by rural electric co-ops. They are more heavily coal than the rest of the utility providers in the country. For the water rule, lots of concern in rural America about how that jurisdiction, if expanded as the EPA suggested, will impact what happens in agriculture and other areas.

Some sense of your level of engagement, not necessarily the FCC rule that we already talked about quite a bit, but are these agencies reaching out to you in a way that you feel is adequate to get your engagement in these important discussions that impact rural America?

Ms. MENSAH. Senator Blunt, thank you for your question.

Yes, I do feel that we are in a dialogue with our sister agencies. You mentioned both clean power and the water rule. We have a strong dialogue. We argue for rural communities. And we feel that when new rules are proposed, we are going to be there for our borrowers to help make any adjustments. So I am happy to answer more specific questions on power or water.

Senator BLUNT. Well, on power, I will ask one. On power, they have now come up with what is the proposed final rule. Has either USDA or your part of USDA taken a position on that final rule?

Ms. MENSAH. Let me ask Administrator McBride to describe to you how we have been working since the final rule has been proposed.

Senator BLUNT. So back to you, Mr. McBride.

Mr. MCBRIDE. Thank you for the question, Senator.

As EPA was developing its rule, we did have conversations with them and let them know our thoughts and how it might impact our programs. In terms of what the final result was from EPA, we do believe that they gave cooperatives additional time and additional flexibility to respond to the rule, so we do feel like they were responsive to the issues that we raised with them. Of course, we do not know the final result until the States developed their own plans. But we do believe that the EPA provided additional time and additional flexibility that will help our borrowers meet the new rule.

Senator BLUNT. At the Secretary level, at Secretary Vilsack's level, are he and the department supportive both of that rule and the other rule I mentioned, the water rule?

Mr. MCBRIDE. The Secretary has been in contact with Administrator McCarthy and others, and believes that we will be able to help our borrowers meet the rules. So the Secretary has been very engaged, and we are working to help our borrowers meet the new requirements.

Senator BLUNT. You do not know whether he has personally endorsed the two new rules or not?

Mr. MCBRIDE. I have not spoken to him directly about that.

Senator BLUNT. All right. I have not either, and I will.

Thank you.

Senator MORAN. Senator Cochran, anything further?

Senator COCHRAN. No, but I want to thank the panel for helping bring life and energy and imagination and hard work to the challenge of improving opportunities for happy and healthy lives in rural America. That is what the Rural Development Act sought to do when Congress adopted it. You are on the frontlines now in carrying out those ideas and suggestions when that act was first approved by Congress.

Thank you for your good efforts.

Senator MORAN. Senator Udall.

Senator UDALL. Thank you, Mr. Chairman.

#### SEQUESTRATIONS IMPACT

Last week, I had the opportunity to travel New Mexico and do some rural economic development meetings. Our State USDA Rural Development State director named Terry Brunner was there and announced some of the grants that go out. I cannot tell you how important those grants are in terms of supporting rural communities, supporting economic development, and really pushing the envelope in terms of helping people be more connected in rural communities with the rest of the State. So we really appreciate what you are doing.

We know that the folks in rural New Mexico need support, need budget certainty, and need adequate resources to fund basic things like water infrastructure, housing, and high-speed Internet, which is not a luxury nowadays. It is actually a necessity.

So let me ask you, Madam Secretary, the USDA Rural Development program is essential for addressing these unique needs, and I am worried that sequestration and the proposed cuts will further obstruct recovery and development. The Committee-passed bill provides \$83 million less for Rural Development compared to the administration's request, and over \$300 million less than was provided in 2010 due to unequal sequestration limits on domestic programs.

What impact will these lower numbers have on your programs and, more importantly, on the families that rely on them?

Ms. MENSAH. Thank you, Senator Udall.

Senator UDALL. You bet.

Ms. MENSAH. I, too, share the concern. Any reduction in our programs hurts rural America. I see these programs. I am out almost every week somewhere with State directors, like you have seen. Every grant dollar that we are able to have the privilege to spend in rural America, I feel we can do it well.

Similarly, the program levels, the loan levels, are being spent very, very carefully. It is a strong portfolio.

So we appreciate anything you can do for our budget request. This is just essential funding for the development of our rural communities.

And I would also say for the kind of State operation we have, you mentioned our State directors, you are supporting a field-based organization in Rural Development. We are not just a Washington organization. That layer of support in every State makes us so

unique, and it is just essential dollars for us. So I thank you for your concern. I share it.

Senator UDALL. Thank you. And you are absolutely right. One of the things that I think really works is, with these State directors, they work creatively with rural communities in order to do the things that they need done, to become better communities, to get people more hooked up, whatever it is. It is a good program, and it is a dramatic example of why we should be out of the sequester.

I mean, sequester hurts these rural communities, and we need to get back to adequate funding for these important programs.

#### SUBSTANTIALLY UNDERSERVED TRIBAL AREAS PROGRAM

Now, Administrator McBride, I applaud your efforts in moving forward with the Substantially Underserved Tribal Areas (SUTA) loan program provisions in the farm bill. Thanks to this program, the Mescalero Apache Telecom company was a recipient of a \$5.4 million loan to make telecommunication improvements for thousands of rural customers.

This type of investment is critical to ending the digital divide in tribal communities.

I will never forget, on this digital divide in tribal communities, when President Clinton tried to show the digital divide, he started out one day in Silicon Valley and ended up the day in Shiprock, New Mexico. In Silicon, they are obviously wired. In Shiprock, he was introduced by a young lady who was a top student in the school in Shiprock, and she had won a computer, but she was unable to even have access with that computer to the Internet. So that highlighted the digital divide in this country.

So that is why this program is so important, the Substantially Underserved Tribal Areas program. I think we need to keep that strong.

Can you describe for us the importance of loan programs such as SUTA and provide suggestions on ways we can expand on efforts to bring modern broadband infrastructure to tribal communities?

Mr. MCBRIDE. Thank you for the question. I was in Mescalero in August. Terry Brunner, your State director, took me around. It was a great project, and they are doing great work there.

We are trying to increase our outreach efforts. It is, certainly, a priority for us to make sure that the tribal areas know about our programs and their availability. It is, certainly, a challenge, expanding broadband into the most rural, most remote areas, but we believe that our partnership with the groups that we worked with before is strong, and there may be ways that we can share some lessons learned that might help other tribal areas expand their access.

Senator UDALL. Thank you very much.

Thank you, Mr. Chairman.

Senator MORAN. Thank you, Senator Udall.

Secretary Mensah, thank you very much for joining us.

Mr. Hernandez, Mr. McBride, Mr. Rikkers, thank you very much.

We will turn to our second panel.

Madam Secretary, there are a couple things we want to follow up with you.

Ms. MENSAH. Yes, I look forward to that.

Senator MORAN. I would invite Mr. Simpson, Mr. Lowry, Mr. Boisvert, Mr. Chrisman, to the table.

We have four experts from across the country with us today. We are delighted to have you here. I will defer in a moment to the Senator from Mississippi, Senator Cochran, to introduce one of our panelists. But I would welcome them all, including Mr. Simpson.

But, Mr. Lowry, thank you very much for joining us. Mr. Lowry is the president and chief executive officer of Sunflower Electric Power Association in Hays, Kansas.

Brian Boisvert is the president and general manager of Wilson Communications in Wilson, Kansas.

And Mr. Tony Chrisman is the vice president and owner of Chrisman Development, Inc., Enterprise, Oregon.

The Senator from Mississippi.

Senator COCHRAN. Mr. Chairman, I am pleased to join you in welcoming our panelists, particularly Bill Simpson, who is a friend of longstanding. His father was legendary for getting things done in Washington as a member of the staff for Senator Jim Eastland, who I replaced in the U.S. Senate when he retired.

So this is a chain of command operation here. And if it looks like we are double-teaming you, we are, because in our State of Mississippi, I do not know of any piece of legislation or Federal program that has been more helpful and enriched the lives of so many as the Rural Development Act. I mentioned it in my questions and observations to the previous panel, when they were here.

But this is also an indication of Congress' response and willingness to help in a positive way enrich the lives of people and create opportunities for economic growth and development, and generally the well-being of those who live in the small towns and rural communities of our great country.

So thank you for helping carry on this great tradition, and we appreciate your good efforts. Thanks.

Senator MORAN. Thank you, Senator Cochran.

We will work our way across the table, and we will begin with the testimony of Mr. Simpson. Thank you.

**STATEMENT OF WILLIAM SIMPSON, DIRECTOR OF LEGISLATIVE AND REGULATORY AFFAIRS, NATIONAL RURAL WATER ASSOCIATION**

Mr. SIMPSON. Thank you, Chairman Cochran, Chairman Moran, Ranking Member Merkley. I am delighted to be here. Good morning. It is an honor to testify before the Subcommittee on Agriculture, water and waste programs, and the associated technical assistance that benefit the small rural communities that chairman Cochran referred to.

As a native Mississippian, I am also extremely proud that this Rural Development title has helped my home State. From the top of the State to the bottom, you can see the tangible effects. Thank you for that.

Before I get started, I wanted to offer a personal note about the subcommittee. One of the great honors in my life was to serve on this subcommittee. I was trained by a former clerk named Galen Fountain, a brilliant, kind, and decent man. He told me in the very beginning working on this subcommittee, you will work in a bipartisan fashion. You will sit at the table with the entire staff. Every

word, every policy, every dollar will be jointly agreed upon. It made the Senate bill stronger, in my humble opinion, and it really made a difference.

In a time when people criticize Congress for not adhering to their duties, I think that this subcommittee, in particular, needs to get the recognition they deserve in taking that stance and, throughout the leadership changes of this subcommittee, continuing on that path. I think this subcommittee should be recognized, commended, and duplicated for that activity.

We have witnessed the reduction and restructuring of Rural Development, and its predecessor Farmers Home, field structure. Under Secretary Mensah mentioned it. I want to reinforce her comments. I know this budget climate is extraordinary difficult, but that is what I saw always as one of the strengths of Rural Development over Federal agencies is that they are out there in the communities. They live and work there to carry out the programs that you appropriate here, and the policies, including the farm bill. I know that really makes a difference.

We share a mission with our Rural Development partner. It is a shared mission that every rural community, regardless of income and location, deserves to be served. And no one in Rural Development should be left behind.

Our seasoned employees at the Rural Water Association have 23 years of experience working in water and wastewater industry. Many of these folks could get other jobs that do not require extensive travel away from their home, but their passion and their love for this industry, and the work, and they get great satisfaction out of helping these rural communities. And the communities we help, quite frankly, do not have a lot of the capacity or expertise to do this activity without this experienced personnel.

We accomplish this mission under three titles under the Rural Development title program with three programs.

First is the Circuit Rider program. I hope you have all heard about that. Since 1980, this on-the-ground assistance to rural communities for water, wastewater infrastructure, it is across the myriad of issues they have, complying with State and Federal regulations, disaster response, rate studies, operations and management. We have 117 circuit riders throughout the country. As you all know, they also do emergency response.

We believe there is a direct correlation with the work that our folks do and the extraordinarily low default and delinquency rate of the water and waste program that you appropriate.

The second is the Wastewater Technical Assistance Program, similar to the Circuit Rider, but it is concentrated on wastewater treatment facilities. We help with design, upgrades, daily operation, maintenance. We have 70 technicians around the country in that area.

Third, we have to commend the Rural Utilities Service for this. They started up a new energy efficiency program. The cost of electricity for a rural utility is the second highest cost behind labor. We started that as a demonstration. We are up to nine States now. We have had really good results in the beginning. We are returning \$4.36 for every \$1 of Federal investment to pay for our expertise, our person out there in the field doing this.

I close with a suggestion for the subcommittee, and it is the current underlying statutory authority for 10,000 population for eligibility for this program. In the past, this subcommittee could put these communities, if they had slightly grown or exceeded the limit, in a general provision. So now we are looking at the demographic change in rural America, people moving out, going into suburbanized areas that are ineligible, but these communities are still rural in characteristic. We would suggest that this subcommittee take a serious look at that.

In summary, rural America has been strengthened by the work and the vision of this subcommittee. No community can grow without sustainable resources, water and wastewater services. We stand with our Rural Development partner to work in this arena and do anything that you ask us to do.

Thank you, Chairman Moran, Ranking Member Merkley, Chairman Cochran. I will answer any questions that you may have.

[The statement follows:]

#### PREPARED STATEMENT OF WILLIAM SIMPSON

Good Morning Chairman Moran, ranking Member Merkley and members of the Subcommittee. It is an honor to testify before you on the Department of Agriculture's Water and Wastewater programs and the associated technical assistance programs that directly benefit small rural communities. As a native Mississippian, I am proud of the work of this Committee and specifically the impact of the Rural Development programs that have lifted-up the quality of life for so many of the residents in my home State from the Gulf of Mexico to our northern border with Tennessee. Thank you.

Before I get started I would like to offer a personal note. One of the great honors in my life was to serve on this Subcommittee. I was trained by a former clerk named Galen Fountain who is a brilliant, kind and decent man. I learned early on that this Subcommittee, regardless if you are in the majority or minority, is tasked to work as a team in a true bipartisan manner to draft and establish the policy and funding levels within your annual allocation—with everyone at the table throughout the entire process, every word, every policy, every dollar would be mutually agreed upon.

In a time where it is popular to criticize Congress on their lack of progress or inability to perform their duties, this Subcommittee is a shining example of how Congress meets those challenges and responsibilities even through difficult times. The entire staff, majority and minority, are recognized as capable, approachable, intelligent and true professionals. The fact that this tradition continues throughout the changes in the leadership of this Subcommittee over the years should be recognized, commended and duplicated.

The Rural Development mission area has a wide and holistic approach necessary to enhance and protect the health and vitality of rural America. We look at these USDA investments, especially in water and wastewater infrastructure, and witness their tangible impact on the quality of life in these rural communities. People take it for granted that their water is always safe and uninterrupted. This is not just about digging trenches and putting pipes in the ground. These investments are the catalyst for economic and community growth. They provide direct benefits like employment opportunities for residents. They also provide indirect benefits like increasing the tax base to attract new businesses and housing developments. Without the advantage of water and wastewater services these foundations of a community would never be put in a position to succeed.

The current water and waste disposal grant and loan programs operated by the Department of Agriculture's Rural Utilities Service have a long and successful history of providing critical infrastructure assistance to meet one of the most basic needs in rural America—providing safe and affordable water and wastewater assistance to low and moderate-income communities. This is one of the highest rated government programs in history, and one with a default rate that is almost non-existent with a greater than 30 day delinquency rate of .42 percent and greater than 1 year delinquency rate of .17 percent. The portfolio consists of over 16,000 loans that are valued at approximately \$12.5 billion dollars. We believe the technical assistance provided by this Subcommittee to organizations like the National Rural

Water Association and others has a direct correlation with the stability and health of this portfolio and protects the government and community's investment.

All communities have elected and/or non-elected leaders that want to improve the quality of life where they work and live so their family and friends can benefit. The Rural Development staff lives and works in many of these same communities. They are part of the fabric of that community and also a vital Federal partner. This partnership has tremendous benefits, whether it's by providing critical infrastructure, securing affordable rental housing, providing broadband, telemedicine, constructing a health care or child care facility or attracting and creating new businesses, it has and continues to impact lives.

We have witnessed the restructuring and reduction of employees and offices in Rural Development and its predecessor, the Farmers Home Administration. I know it is difficult in this budget climate, however any efforts to preserve or enhance this field structure will make a difference in serving remote rural areas especially ones that experience pervasive poverty. You can see diminishing Rural Development housing, water infrastructure and other loan and grant activities in areas where staff and offices have been reduced, relocated or eliminated.

The National Rural Water Association also shares a mission with our Rural Development partner. A shared mission to serve every rural community in need regardless of income or location. Like Rural Development, we want to ensure no community in rural America is left behind. Our seasoned field employees have an average of 23 years of experience working in the water and Wastewater industry. Many could find higher paying jobs and positions that did not require extensive travel, but they are on a mission and receive great personal satisfaction from their work. Many of the communities we serve simply can't afford the individual expertise necessary to operate and maintain their utility systems.

We accomplish this mission by using three existing programs under the Rural Development Title.

- First, the Circuit Rider program. Since 1980, Circuit Riders have provided on-site technical assistance to small rural communities for water infrastructure development, compliance, training, certification, operations, management, rate studies, disaster response, public health protection—all necessary to encourage local responsibility and local solutions for protecting and enhancing water resources. This mission is simple. At the grassroots level we deliver on-the-ground assistance to communities in need by providing safe, affordable and sustainable water service. We currently have 117 Circuit Riders throughout the country. From Dec 1, 2014 to September 30, 2015, Circuit Riders directly assisted 22,143 rural water systems through 40,788 direct contacts totaling 207,607 hours of work. This work performed by NRWA far exceeds our contract requirements. Rural communities also rely on our circuit riders in emergency situations. When flooding, extreme freezing, tornados or hurricanes hit, the circuit riders reach out to rural systems with generators, and technical help and assistance to get systems back online and safe water flowing to their customers.
- Second, is the Wastewater Technical Assistance program. This initiative provides on-the ground technical assistance directly to communities for wastewater treatment facilities. Assistance includes design and upgrade recommendations, daily operation and maintenance advice, assisting with permit renewals and helping these systems meet compliance requirements from state and Federal regulations. We currently have 70 wastewater Technicians throughout the nation. The wastewater Technicians, from July 1, 2014 to June 30, 2015, provided 147,571 hours of work directly contacting systems 35,969 times to assist 7,746 wastewater systems.
- Third, we are in our 2nd year with a new energy efficiency program created by the Rural Utilities Service (RUS). With electricity as the second leading operational cost after labor for a utility, reducing this expense provides increased stability and frees up revenue to address upgrades or deferred maintenance and at the same time reduces the burden to shift ever increasing operational costs to the moderate or low-income customers. We started this initiative last year with seven states and expanded to nine states this fiscal year. From July 1, 2014 to June 30 2015, 240 assessments were completed with a combined energy savings of \$2,615,809. This initiative returns \$4.36 in savings to the utility for every \$1 of Federal investment.

I will close with a suggestion for the Subcommittee. The current underlying statutory authority for the Rural Development Water and Wastewater programs is set at a 10,000 population limit. The Secretary has little flexibility or waiver authority to address communities that have grown or slightly exceed that limit. In the past, this Committee was able to list these communities in general provisions in order to continue to be eligible for the RUS Water and Wastewater programs.

With the changing demographics of rural America, we believe that increasing the population limit to 20,000, with a priority given to smaller communities, would provide a benefit to rural America. We also believe this will increase the utilization rate for the Water and Wastewater Guaranteed program especially for communities with more resources and capacity necessary to debt service a commercial market rate loan.

In summary, rural America has been strengthened from the work and vision of this Subcommittee. No community can grow and improve without the sustaining resources of water and wastewater services. Rural Water stands willing and able to work with you and our partners at Rural Development to accomplish this goal.

Thank you Chairman Moran and Ranking Member Merkley for allowing me to testify and I would be happy to answer any questions that you may have at this time.

Senator MORAN. Mr. Simpson, thank you.

Mr. Lowry, before you testify, on behalf of my colleagues, I want express my care and concern for the president and CEO of the National Rural Electric Cooperative, Jo Ann Emerson. Her health is a very challenging circumstance. I served in the House of Representatives where classmates and many of my colleagues are great friends of Jo Ann. And we express, on behalf of all of us, to her and her family and the folks at the Rural Electric Cooperative Association, our love and compassion for Jo Ann.

Mr. LOWRY. We will be certain to pass that on to her. I know that it will be welcomed and well-received. Thank you very much.

Senator MORAN. Thank you.

**STATEMENT OF STUART LOWRY, PRESIDENT AND CHIEF EXECUTIVE OFFICER, SUNFLOWER ELECTRIC POWER ASSOCIATION**

Mr. LOWRY. Mr. Chairman, thank you for allowing me to be here today. Ranking Member Merkley, Senator Cochran, I appreciate the opportunity to be here to talk about 21st century rural development.

As Chairman Moran mentioned, my name is Stuart Lowry. I am the president and CEO of Sunflower Electric Power Corporation in Hays, Kansas. We are a generation and transmission cooperative, much like PNGC would be in the State of Oregon, or South Mississippi would be in the State of Mississippi. We provide wholesale services to over 350,000 Kansans.

I am also here representing the National Rural Electric Cooperative Association, the organization that Jo Ann Emerson heads up. That is the service organization for over 900 not-for-profit electric cooperatives in over 47 States that provide electricity to roughly 11 percent of the Nation's population. The development of the electric co-ops is really a perfect example of fostering rural economic development.

The story of the Rural Electrification Administration (REA) effort to electrify rural America via electric cooperatives is well-known to everybody by now. The agency is now known as the Rural Utilities Service, and this agency and its programs have allowed electric cooperatives to become champions for strengthening rural America beyond just providing electric service.

The Rural Economic Development Loan and Grant program, commonly referred to as REDLG, is an excellent example of a tool used by cooperatives to promote rural development.

The loan program provides zero-interest loans to local utilities that they then pass through to small businesses for projects that generate local revenue and jobs. The grant program allows local co-

operatives to establish revolving loan programs for other community projects.

In 2015, the loan program directed loans to 29 cooperatives for energy efficiency projects, rail offloading equipment, ambulances, and renovations for retirement communities. In addition, 27 grants went to 18 cooperatives, which renovated schools, hospitals, financed fire equipment, purchased medical equipment, and updated 911 communications equipment.

Kansas has many examples of REDLG success stories, but recently, two Kansas cooperatives well-known to Chairman Moran, Prairie Land Electric and Western Cooperative Electric, both used their revolving loan funds to purchase a CT scanner for the Sheridan County Health Complex. This adds a tremendous health benefit to a community of roughly 1,200 people. Similar examples exist in many other States, as well as the State of Kansas.

REDLG's successes have generated a greater demand for funding. We greatly appreciate the chairman and subcommittee for recognizing this challenge.

One critical source of funding for the REDLG program are the fees paid by cooperative lenders under the guaranteed underwriter program. The fees currently deliver \$13 million annually. Two very important lenders to electric cooperatives, the National Rural Utilities Cooperative Finance Corporation, or CFC, and CoBank, have accessed funding through the Guaranteed Underwriter Program and have used these funds to help finance electric cooperatives investment in rural utility infrastructure projects. Fees from these transactions help fund the REDLG program.

Additionally, rural America is increasingly capitalizing on programs for energy efficiency. Over 96 percent of cooperatives already provide these programs to their consumer members. Both the 2008 and 2014 farm bills included programs for RUS to help cooperatives increase energy efficiency for the benefit of their customers.

Much credit is owed to this subcommittee, particularly Ranking Member Merkley, for his leadership to enact the Rural Energy Savings Program Act.

A robust regulatory agenda in recent years, and increased bureaucracy, have admittedly been burdensome and challenging. In the Great Plains region Sunflower serves, we are concerned about recent regulatory initiatives, including those under the Endangered Species Act and the lesser prairie chicken.

While the courts are considering various appeals, we continue to study the cost implications of listing the bird as threatened or endangered. Costs imposed on utilities via regulation are passed on to ratepayers, thus increasing the affordability of the service that we provide.

This is just one more example of how rural cooperatives must pass costs on to our members in the face of overregulation.

RUS finances future and improved distribution, transmission, and generating systems. We are particularly concerned that as a result of overregulation we will be required to spend more of these dollars on regulatory compliance costs. As such, it is vital that utilities spend their time providing safe, affordable, reliable electricity and using REDLG programs to contribute to a better rural America.

Sunflower, NRECA, and the cooperatives across the country greatly appreciate this subcommittee and the full committee support for funding the RUS electric loan program at the \$6 billion level for fiscal year 2016.

Thank you also for recognizing the value that these programs provide the rural communities we serve.

Thank you for inviting me here to testify. I look forward to any questions you may have.

[The statement follows:]

#### PREPARED STATEMENT OF STUART LOWRY

##### INTRODUCTION

Thank you, Chairman Moran, Ranking Member Merkley, and members of this subcommittee for inviting me to testify today at your hearing on the Importance of Rural Development and, more specifically, on USDA's Rural Economic Development Loan and Grant (REDLG) program.

I am Stuart Lowry, president and CEO of Sunflower Electric Corporation in Hays, Kansas. Sunflower is a not-for-profit, wholesale electric generation and transmission utility, commonly known as a G&T. Based on the cooperative business model, Sunflower is owned and democratically governed by its member-owners, six distribution cooperatives serving more than 350,000 members in central and western Kansas. Sunflower and its Distribution Cooperative Members provide more than 800 jobs in communities located in the western half of Kansas.

I am also here today representing the National Rural Electric Cooperative Association (NRECA). NRECA is the service organization for more than 900 not-for-profit electric utilities serving over 42 million people in 47 states. NRECA's members include 67 G&T cooperatives that generate and transmit power to 66 of the 838 distribution cooperatives across the nation. Electric cooperative service territory makes up 75 percent of the nation's land mass. Kilowatt-hour sales by rural electric cooperatives account for approximately 11 percent of all electric energy sold in the United States. NRECA member cooperatives serve over 42 million Americans, including more than 8 million member owners and 11,839 jobs in the 12 states represented on this subcommittee.

I would like to thank the Chairman, Ranking Member, and the entire subcommittee on behalf of Sunflower and NRECA for their long-standing support of rural electric co-ops and their consumer-members. We are also grateful for Administrator McBride's leadership and service to cooperatives.

##### ELECTRIC CO-OPERATIVES AND RURAL DEVELOPMENT

The development of electric co-ops is a perfect example of rural development. As many of you know, well into the 1900s, a lack of economic incentives left much of rural America literally "in the dark"—unserved by private power companies. This led to President Roosevelt's forming the Rural Electrification Administration, then known as the REA, in 1935 to establish programs that would lead to the electrification of rural America via electric cooperatives. Now restructured as the Rural Utilities Service to include other rural utilities—such as those represented on this panel—RUS continues to operate programs that benefit rural America under the umbrella of Rural Development at USDA. Combined, these programs have allowed electric co-ops to play a major role in strengthening small communities that are essential not only to the nation's economy, but also to the way of life valued by many.

Electric co-ops continue to take seriously the seventh cooperative principle: Concern for community. The economic development work in Rural America is not done and we appreciate the Subcommittee focusing its attention on this important topic.

In June, NRECA convened a Rural Summit here in Washington. The event gathered rural experts from the Administration in various Federal departments, non-profit groups, academia, and other rural leaders to hold a positive conversation about how to tackle the toughest issues facing rural communities and main street economies. The next steps are to take the Summit on Rural America into regional discussions around the country and to populate a guidance group that can collect and share best practices and ideas and explore a number of themes.

One theme is harnessing the value of the multiple profiles and changing demographics of rural America. Another is growing interest in the assets in rural America and investing in the infrastructure and technology to connect rural America with the world. Participants also highlighted the need for new ways of doing business

and developing educational opportunities and a workforce to conduct that business. Other panelists highlighted the quality of rural life and the need to address the public's perception of "rural." These regional gatherings are expected to focus on growth and diversification of the local economies, the expanded role for technology in the rural economy, and the need to focus on collaboration and communication.

Twenty-five years ago, NRECA was instrumental in forming the National Rural Economic Developers Association, an organization that provides education and networking for professionals who work to grow our rural communities. NREDA has been very active promoting and providing education for USDA programs, especially the Rural Economic Development Loan and Grant Program.

REDLG is one of the programs that co-ops have utilized to help enhance small-town America, and Kansas is just one of the many success stories. REDLG is a \$33 million loan and \$10 million grant program available to co-ops for economic development activities. The loan program provides zero interest loans to local utilities that serve as a pass through to small businesses for projects that create and generate new jobs and revenue. The grant program provides funds to local cooperatives that use the dollars to establish revolving loan programs for specific projects. Once the loan is repaid to the revolving loan fund, the cooperative continues to deploy the funds for additional rural development projects.

In 2015, the loan program directed \$32.5 million in loans to 29 coops that created 288 jobs and saved 436 more. These dollars enabled energy efficiency projects, purchased rail offloading equipment, ambulances, a library expansion and retirement communities. In addition, 27 grants went to 18 co-ops for \$7.1 million, which renovated schools and hospitals, financed fire equipment, built fire halls, purchased medical equipment, and updated 911 communications equipment. The grant program saved 151 jobs and added 112 more.

A specific example of the ways Kansas cooperatives have used this program includes

Prairie Land Electric, headquartered in Norton, Kansas, and Western Cooperative Electric, headquartered in WaKeeney, Kansas, using funds from their revolving loan funds for the Sheridan County Health Complex, located in Hoxie, Kansas (population 11,201). The funds are being used for hospital upgrades, including the addition of a CT scanner, so this small community can enjoy improved access to healthcare. Together the cooperatives loaned \$575,000 to the health complex for this project.

Recently, Twin Valley Electric Cooperative from Altamont, Kansas, was awarded a \$200,000 REDLG loan for RBK Manufacturing LLC in Coffeyville, Kansas (population 10,295). This successful manufacturer of aftermarket auto parts and equipment will purchase additional tooling equipment for expansion. The four additional jobs provided by this expansion are important in small communities like Coffeyville.

These are excellent examples of how the REDLG program continues to provide benefit to rural America. Kansas cooperatives are in good company with the many other electric cooperatives that have used this program to improve their community.

In Iowa, Corn Belt Power Cooperative and Butler County REC each loaned \$60,000 from their respective Revolving Loan Funds to assist Allison Family Dental. Dr. Travis Harbaugh had just graduated dental school and purchased the existing dental practice in Allison, Iowa (population 1,025) from a retiring dentist. The purchase allowed a dental practice to remain open in a rural community, retain three jobs, and create four more.

Sioux Valley Energy in South Dakota provided funding for the Lake Area Improvement Corporation to construct the Heartland Technology Center in the Hueners Technology Park. The technology park is in Madison, South Dakota, (population 6,474). The Center has office space designed to meet the needs of businesses needing a high-tech setting and is located adjacent to nationally recognized Dakota State University to provide immediate access to some of the best qualified baccalaureate and masters graduates in computer science and information systems.

An expansion for Brownmed Inc., headquartered in Spirit Lake, Iowa, (population 14,952), allowed the company to more than double its existing manufacturing facility of 30,000 square feet by constructing an additional 51,000 square feet. The company manufactures more than 85 products for medical purposes, including the Seal Tight Cast, Plastalume finger splint and IMAK arthritis compression products. Total expansion costs were over \$3.6 million. Iowa Lakes Electric Cooperative received a \$1,000,000 Rural Economic Development Loan through USDA for the project, while loaning an additional \$250,000 from their REDLG revolving loan fund. Corn Belt Power loaned \$150,000 from their Intermediary Relending Program (IRP) Revolving Loan Fund toward the project as well. Brownmed employs 66 people, 50 of whom are in the Spirit Lake location. This is an excellent example of cooperatives using multiple USDA programs to create jobs in their communities.

Recently, the list of entities eligible for the program has expanded, which has placed more demand on the funds. The Administration requested a budget of \$60 million, and we would like to see the REDLG program funded as close to this recommendation as possible. We support reducing the maximum loan level to \$1 million as this approach will allow more projects to be funded in rural areas—where a little funding can go a long way.

In recent years past, the REDLG program benefited from millions of dollars in unused funds carried over from previous years, dwindling dramatically from \$57.9 million in fiscal year 15 to only \$8.2 million in fiscal year 14. We appreciate the Subcommittee's efforts to make these funds available after the year in which they were appropriated. Unfortunately, given the high demand on the program, all funds have been used during the fiscal year. If in the future, any funds remain unused at the end of the year, we hope the Subcommittee will provide the opportunity to carry-over funds to the following year in support of the REDLG program.

#### GUARANTEED UNDERWRITER PROGRAM

One critical source of funding for the REDLG program is the fees paid by cooperative lenders under the Guaranteed Underwriter Program. The level of fees is currently at \$13 million.

We appreciate this subcommittee's work to increase the Guaranteed Underwriter Program to \$750 million in the fiscal year 16 bill. This increase supports electric cooperatives by helping cooperative lenders maintain a balanced portfolio to provide loans at attractive rates as well as increasing the level of fees paid to support the REDLG program.

Since 2005, the National Rural Utilities Cooperative Finance Corporation (Cooperative Finance Corporation) has accessed funding through the Guaranteed Underwriter Program and used the funds to help finance electric cooperatives' investment in rural utility infrastructure projects such as poles, wires and substations. As part of its long term commitment to the Guaranteed Underwriter Program, CFC also pays fees to help fund the REDLG program. Recently, another lender, CoBank has also utilized this program.

#### ENERGY EFFICIENCY

RUS has recognized energy efficiency as an integral component of electric cooperatives' energy resources. Co-ops have long been leaders among utilities in the area of energy efficiency with 96 percent of co-ops already providing some energy efficiency program to its consumer-members.

Both the 2008 and 2014 Farm Bills included ways that RUS could help co-ops increase energy efficiency for the benefit of their consumers. The Energy Efficiency and Conservation Loan Program (EECLP) and the Rural Energy Savings Program (RESP) are designed to help co-ops promote energy efficiency and renewable energy to their consumers, saving energy while also saving consumers money on their energy bills. One such example is Midwest Energy Cooperative, located in Hays, Kansas, which was among the first co-ops in the country to provide on-bill financing for energy efficiency improvements for their consumer-members.

These energy efficiency programs have a positive financial impact on communities because they create jobs in rural areas and increase economic activity due to savings resulting from energy efficiency improvements.

Much credit is owed to Ranking Member Merkley for his leadership on the Rural Energy Savings Program Act (RESPA), and we look forward to working with him and other members of this subcommittee on ways to make these programs most successful.

#### CONCERNS GOING FORWARD

A robust regulatory agenda in recent years and subsequent increased bureaucracy have admittedly been burdensome. Electric co-ops are concerned about having to spend more time figuring out how to comply with new costly regulations and how to avoid passing those costs onto our consumer-owners, all of which leave less time and resources available for innovation and strengthening our existing services.

For example, in the Great Plains region where Sunflower serves, we are concerned about recent developments with the Endangered Species Act and the Lesser Prairie Chicken. While the courts are considering various appeals, we continue to study the cost implications of listing the bird as threatened or endangered. This is just one more example of how rural cooperatives—averaging 7.4 consumers per mile of line and collecting annual revenue of approximately \$15,000 per mile of line versus investor-owned utilities averaging 34 customers per mile of line and collecting \$75,500 per mile—must pass costs to our members. Rural cooperative mem-

bers are older, less financially stable, and fewer in number and thus have limited ability to pay higher electric rates created by the increased regulatory burdens.

The RUS allows co-ops to finance future and improved electric distribution, transmission and generating systems. We are concerned that, as the result of overregulation, we will be required to spend more of these dollars on compliance costs. As such, it is important that RUS is adequately funded so that utilities can spend less time crunching numbers related to compliance costs for providing electricity and more time engaging in other activities and programs, such as REDLG, that contribute to an improved economy and a better quality of life for our members.

Sunflower, NRECA, and co-ops across the country greatly appreciate this subcommittee and the full committee's support for funding the RUS electric loan program at the \$6 billion level for fiscal year 16. Thank you for recognizing the value that the electric program and co-ops provide to approximately 42 million people every day.

We look forward to providing any information that would be helpful to the committee and improving the opportunities or addressing the challenges that face rural America. I thank you for inviting me to testify and look forward to any questions you may have.

Senator MORAN. Mr. Lowry, thank you very much.

We now turn to Mr. Brian Boisvert. Welcome.

**STATEMENT OF BRIAN BOISVERT, CHIEF EXECUTIVE OFFICER AND  
GENERAL MANAGER, WILSON COMMUNICATIONS**

Mr. BOISVERT. Good morning. Thank you, Chairman Moran, Ranking Member Merkley, and Senator Cochran. Thank you for this opportunity to testify before you about rural telecommunications and its impact on rural development.

I am Brian Boisvert, CEO and general manager at Wilson communications in Wilson, Kansas. I have been part of the rural telecom industry for 37 years and with Wilson for the past 15.

Wilson communications is a local telecommunications provider serving 1,500 rural Kansans over a 1,000-square-mile area. We have 17 employees. We provide wireline voice, high-speed broadband, and video services over a fiber-optic-based network. We have been an REA, RUS borrower since 1956, and we have a current loan for our fiber to the home build.

Broadband is an integral element in the 21st century and beyond for rural development. Well-built and maintained broadband networks make it possible to live anywhere and obtain a college degree, be economically successful, receive specialized medical care, and have access to entertainment and shopping not generally available in rural communities.

So-called smart devices are appearing every day. In the home, they monitor and help manage energy consumption, and they can also alert the homeowners that the kids have arrived safely home from school. Rural farming can be more efficient and safe with bin monitors, heat sensors, and fuel tank level alerts.

Regardless of whether it is consumer-based for business or emergency services, it all relies on a well-built broadband network.

As an illustration of the scale of rural broadband build networks, the Kansas rural telecommunication companies serve approximately 10 percent of the population, but our service areas cover 50 percent of the State's land mass. This is typical of rural telecommunication providers all across the Nation.

A business model does not exist for these low-population density areas. This is why a predictable, sufficient, and sustainable Universal Service Fund is critical for rural development. Updated for

broadband-capable networks, USF could have the same successful impact it had when bringing telephone service to every American.

The FCC issued its transformation order in 2011 with the goal to modernize the Universal Service Fund. However, the order created uncertainty throughout the rural telecommunications industry, adversely impacting investments in broadband-capable infrastructure throughout areas served by rate-of-return carriers.

Even as I sit before you today, the rural telecommunications providers still lack certainty for a sufficient, predictable, and sustainable Universal Service Fund. A USF that includes support for standalone broadband service will be a cornerstone in bringing economic benefit for rural development in small communities across the Nation.

We see an ever-increasing connection, an interdependence between rural and urban areas. This relationship can be seen by considering the Nation's farms. The bulk of the Nation's food supply is produced in rural America, but their products supply the entire Nation.

Agriculture, Kansas's dominant economic activity, can benefit greatly from broadband-enabled services. Ag operations can monitor grain prices online to optimize their revenues. And if they are in the cattle business, they can bring their herd to a local sale barn that is now utilizing online auctions. This expands their market to beyond buyers who could only drive to the sale.

The rural telecom industry contributes both to rural and urban economies. Even at the height of the recent recession in 2009, the rural telecom industry contributed \$14.5 billion to the economies in States where they operated. The majority of this economic activity, 66 percent, went to the benefit of urban areas. Jobs supported exceeded 70,000, with 54.3 percent in rural areas and 45.7 percent of these jobs in urban areas.

Building and maintaining these networks is clearly important, but so too is broadband adoption. Combined, I believe it will not only enhance rural development, but is critical to rural community survival.

How do we achieve this? One important factor is the continued availability of RUS loans. Making capital available to small companies at competitive rates is critical for the continued investment in modern infrastructure. The ability to keep rural consumer rates reasonably comparable to urban rates is a key goal of universal service.

Taken together, the availability to capital and ongoing USF support will help ensure rural development in a stronger and connected Nation.

Thank you, Mr. Chairman, Ranking Member Merkley. I am happy to answer your questions.

[The statement follows:]

#### PREPARED STATEMENT OF BRIAN BOISVERT

##### INTRODUCTION

##### *The Rural Telecommunications Industry*

Chairman Moran, Ranking member Merkley, and members of the subcommittee, thank you for this opportunity to testify before you about rural telecommunications and its impact on rural development. I am Brian Boisvert, CEO/General Manager

at Wilson Communications. My remarks today are on behalf of Wilson Communications, as well as NTCA—The Rural Broadband Association and their several hundred small community-based members that provide a variety of communications services throughout the rural far reaches of the nation.

I have been part of the rural telecommunications industry for 37 years and with Wilson for the past 15 years. Wilson Communications is a local telecommunications provider serving 1,500 rural Kansans over a 11,000 square-mile area. Wilson has 17 employees. We provide wireline voice, high-speed broadband and video services over a fiber optic-based network. We have been REA/RUS borrowers since 1956 and have a current loan for our FTTH build.

Small, rural telecom providers connect rural Americans to the world. Moreover, these rural network operators have been at the forefront of the broadband and Internet Protocol (“IP”) evolution for years, making every innovative effort to deploy advanced networks that respond to consumer and business demands for cutting-edge services. In rural America, that translates into economic development that produces jobs, not only in agriculture, energy and other industries with a strong rural presence, but in the healthcare sector, and just about any other retail industry that requires broadband to operate in this day and age. Broadband has become essential to delivering healthcare and securing the public safety. And much of the business world is already demanding higher broadband speeds to help it interact with and sell to customers near and far. Broadband and other services provided by the rural telecom industry serve as an incubator for small business ideas in rural America to be implemented and to flourish.

Fixed and mobile broadband, video and voice are among the numerous telecom services that rural Americans can access thanks to the rural industry’s commitment to serving sparsely populated areas—and the rural development and other essential governmental programs that make it possible to carry out this commitment. Broadband-capable networks facilitate greater interconnection of the community’s resources and can enable citizens’ participation in the global economy, blue-ribbon education, first-rate healthcare, cutting-edge government services, robust security and more efficient energy distribution and use.

The rural telecom industry has always been at the forefront of technological innovation, being the first segment of the industry to completely convert to digital switched systems, provide wireless options to their hardest to reach customers, offer distance learning and tele-health applications, provide cable-based video, then satellite video, and now IP video to their markets, and it was a member of the RLEC community that first deployed an all-fiber system. The rural industry continues to lead in the deployment of broadband capable infrastructure.

#### RURAL BROADBAND BENEFITS THE ENTIRE U.S. ECONOMY

A series of studies confirms that significant benefits flow from rural broadband investment to broader urban and statewide populations. For example, the Hudson Institute has found that investment in rural telecommunications delivers real pay-back for the entire nation, generating \$14.4 billion annually in economic activity as of 2011—\$9.6 billion of which accrued to the benefit of urban areas, and more than 70,000 jobs, 45 percent of which were placed in urban areas.<sup>1</sup> In Colorado, rural telecom helped create 428 jobs, adding over \$21 million per year to state payrolls.<sup>2</sup> North Dakota saw an additional \$18 million in Federal tax revenue and \$31 million in state tax revenue arising out 1,100 direct jobs and 800 secondary jobs generated by rural telecommunications activity.<sup>3</sup>

The converse holds true, however, from adverse changes—“reforms” that depress or cut investment in rural broadband hurt state economies. In Kansas, for example, potential cuts in Federal rural telecom programs were projected to result in \$1.4

<sup>1</sup>Kuttner, Hanns, *The Economic Impact of Rural Telecommunications: The Greater Gains*, Hudson Institute, at 6, 8 (2011).

<sup>2</sup>Shields, Martin, Cutler, Harvey, and Marturana, Michael, *The Impacts of Colorado Telecommunications Association Members on the Colorado Economy*, Regional Economics Institute, Colorado State University, at 9 (Oct. 26, 2011).

<sup>3</sup>McKee, Gregory, *The Effect of Changes in Universal Service Funding on the Economic Contribution of Rural Local Exchange Carriers to the North Dakota State Economy*, Department of Agribusiness and Applied Economics, Agricultural Experiment Station, North Dakota State University, at 16–19 (Dec. 2011) (“Like other RLECs, North Dakota RLECs buy many specialized products and services not available in state economies. National and international markets typically provide these products and services.”).

million in personal income tax losses and \$1.3 million in retail sales tax losses.<sup>4</sup> A personal income loss of \$14.1 million was projected for 2012 alone in New Mexico from the same proposed cuts.<sup>5</sup> Studies examining the impact of rural communications activity—including purchasing, employment figures, and projected tax revenues—confirm rural communications to be a powerful generator of urban economic growth and Federal and state tax revenue. In short, rural broadband is an investment with real benefit and returns for the nation as a whole.

To not have access to high-speed Internet in this day and age is unimaginable to most people, yet millions of Americans live in areas—mostly in rural territory served by carriers other than small, rate-of-return providers similar to Wilson—where there is no robust broadband that enables meaningful access to the countless economic and educational opportunities available through the Internet. These people have small business ideas that need broadband to succeed and they need jobs that small businesses can provide. Yet, as important as it is to deliver broadband to the unserved, it's equally vital that those already receiving broadband remain served—the benefits that flow from broadband are ongoing. If a network is built in a rural area but then becomes unsustainable or the services over it unaffordable or of poor quality, such developments deny the benefits of broadband for small businesses and all consumers. Thus, the mission of universal service—and the economic benefits it delivers locally and to the nation as a whole—require ongoing operations, effort, and support to be realized.

#### RURAL UTILITIES SERVICE FINANCING

##### *RUS Role in Rural Telecom Deployment*

USDA's Rural Utilities Service (RUS) plays a crucial role in rural broadband deployment through its telecommunications programs that finance network upgrades and deployment in rural areas. RUS has been lending for broadband capable plant since the early 1990s. RUS lending and Universal Service Fund (USF) support are inextricably linked as more than 99 percent of RUS Telecommunications Infrastructure borrowers receive high cost USF support. The presence of high cost recovery through USF support is therefore crucial to the RUS telecom and broadband loan calculus. RUS programs have helped rural providers deploy modern networks in many rural areas where the market would otherwise not support investment. Reliable access to capital helps rural carriers meet the broadband needs of rural consumers at affordable rates.

Unfortunately, the success, momentum, and economic development achieved from the RUS's telecommunication programs were put at risk as a result of the regulatory uncertainty arising out of USF reforms—some enacted, some revoked, and some still pending consideration—which are discussed in greater detail below. It will be all the more important to continue providing RUS with the resources it needs to lend to the rural telecom industry as demand for financing should increase when reforms are improved and small carriers are given certainty, hopefully through targeted updates to the existing USF programs designed to re-establish clarity and promote broadband investment. As Congress continues to grapple with where to best direct scarce resources, it's important to note that the RUS Broadband Loan Program and the traditional Telecommunication Infrastructure Loan Program make loans that must be paid back with interest—creating a win/win situation for rural broadband consumers and taxpayers. Rural providers look forward to building on an already successful partnership with RUS.

##### *Appropriations*

We appreciate the Appropriations Committee's efforts to ensure the FCC continues to receive direction with respect to USF cost recovery support and making sure that the RUS Telecommunications Program is adequately funded. The committee agreed as well with NTCA's request to extend the prohibition on the FCC from subjecting USF to the Federal Anti-Deficiency Act through December 31, 2017, and to extend the long-running prohibition on any sort of primary-line restriction on USF support through the end of fiscal year 2016. The committee further agreed to reject the Administration's budget request to divert \$25 million in USF funds for additional unnecessary reviews and investigations in the wake of a series of earlier costly audits that identified no noteworthy program issues to begin with. This sub-

<sup>4</sup>Kansas Rural Local Exchange Carriers: Assessing the Impact of the National Broadband Plan, W. Frank Barton School of Business, Center for Economic Development and Business Research, Wichita State University, at 11, 12 (2011).

<sup>5</sup>Peach, James, Popp, Anthony V., and Delgado, Leo, The Potential Economic Impact of the National Broadband Plan on the New Mexico Exchange Carriers Group, Office of Policy Analysis, Arrowhead Center, New Mexico State University, at 18 (2011).

committee also favorably responded to NTCA's request for report language directing the FCC to complete the development of a fully functional, broadband-oriented USF program for rural rate-of-return carriers. Mirroring language was also included in both the FCC bill and the RUS appropriations bills directing the two agencies to work together to ensure that the USF and RUS programs operate in a coordinated fashion rather than to the possible detriment of one another. Clearly this subcommittee played an integral role in developing each of these initiatives and ensuring they were a part of the package agreed to by the full committee, and we applaud your leadership.

#### UNIVERSAL SERVICE

##### *The FCC's Universal Service Fund Reforms*

RUS programs represent one important side of the coin—governmental programs intended to provide capital to enable investment in infrastructure in rural areas. As mentioned earlier, however, there is another, equally important side of that coin—governmental programs intended to ensure that networks, once deployed, can be maintained and upgraded, and that services offered atop those networks will remain affordable and of high-quality for consumer adoption and use.

No issue is perhaps more important to the fundamental capability of small telcos to deliver services in high-cost, sparsely populated rural markets than the availability of sufficient and predictable universal service support. The ongoing availability of USF support is essential to ensure that rural telcos can make the business case to invest in robust advanced networks, to enable the operation of those networks over many years, and to facilitate consumer use of services at affordable rates. (USF support is, in this regard, an essential complement to RUS programs that only serve to finance network construction in the first instance.) NTCA has made substantial efforts to restore regulatory certainty to the USF program, and has sought thoughtful upgrades to the USF mechanism consistent with a broadband-oriented world.

For rural areas like those served by Wilson Communications and other NTCA members, FCC rules still require customers to purchase landline voice telephone service in order for their connection to receive USF support. The customer is thus effectively denied the option of cutting the landline-voice cord and purchasing only broadband. Such outdated rules that undermine consumer freedom and inhibit technological evolution present an obstacle to the technology transition that consumers and industry are making and the FCC is working to expedite and facilitate in other contexts. While Universal Service programs should certainly support and require the offering of voice services, it should not compel consumers to buy voice to obtain affordable broadband. The FCC should move forward immediately to adopt and implement a carefully tailored update of USF that will provide sufficient and predictable support for broadband-capable networks in areas served by smaller rural carriers. Earlier this year, over 175 members of Congress (including 61 senators) wrote to FCC Chairman Wheeler, urging him to make targeted fixes to the existing USF mechanism to solve “the standalone broadband problem.”<sup>6</sup>

The FCC is in the midst of considering such reforms now, and has made commitments to many in Congress to take action on “the standalone broadband problem” by year's end. We have been working closely as an industry with the FCC and other stakeholders to make this a reality. It is key, however, to ensure at the same time that these reforms are undertaken thoughtfully, with an understanding of the consequences of specific changes on investment incentives, access to capital, and ultimately consumers. As an industry that lived through a series of reforms in 2011 that created confusion and uncertainty and ultimately only depressed investment—until Congress helped to push the FCC to roll back some of the worst parts of that reform—it is essential to rural telcos that reform both gets done quickly and gets done right. We hope that the FCC will find a way to deliver on the requests of Congress to fix the standalone broadband problem, and we are committed to staying at the table to come up with a solution that responds to that call, fulfills shared principles for reform, and ultimately comports with the statutory mandates for a sufficient and predictable support mechanism that enables the offering of reasonably comparable services at reasonably comparable rates in rural and urban America both.

The broadband revolution presents major opportunities for small businesses to innovate and grow, but the business (or entrepreneur with an idea) must have

<sup>6</sup>See US Senate letter led by Senators Thune and Klobuchar dated May 11, 2015 and US House letter led by Representative Kevin Cramer dated May 12, 2015, both sent to FCC Chairman Wheeler.

broadband access to take full advantage. Markets will ensure many consumers realize the full benefits of innovation at the lowest possible prices, but in rural areas there are often no such markets to speak of. Though small, rural providers have been leaders in broadband investment under the current statutory and regulatory regime, further law and policy changes will be necessary to ensure high cost rural areas remain served. A faithful and disciplined approach to the core Communications Act principle of universal service must therefore ensure that, even in the event of any statutory or regulatory update, those areas served through support from Federal and state USF mechanisms not only “become” served in the first instance, but that they “remain” served, and that consumers and businesses everywhere can make full use of sustainable advanced communications services at affordable rates.

Finally, Congress should consider an express directive to the FCC to ensure that all who use our nation’s networks—by whatever service or technology—are responsible to contribute to the universal well-being and availability of those networks on an equitable basis. USF is still funded by assessing interstate and international long distance telephone service. The pool of assessable telecommunications service revenues is shrinking even as overall communications-related revenues grow. As a result, the USF program effectively has an artificial funding ceiling that lowers a bit each day due to the failure to broaden the contribution base. This de facto cap on the USF program will handicap severely our nation’s ability to fulfill the statutory core principles unless changes are made. Indeed, broadening the contribution base to include the services that USF already supports has previously received bipartisan backing in the US House.<sup>7</sup>

#### CONCLUSION

Entrepreneurial small rural carriers have leveraged public and private capital, universal service support, and public-private partnerships to lead the ongoing IP Evolution. These small businesses play an essential role in deploying broadband to rural areas, and the services enabled by broadband are essential to the startup, operation, and growth of other rural small businesses. Rural America has a bright future powered by smart technologies that promote affordability, sustainability, and efficiency in the operation of rural industry and the delivery of essential services such as healthcare, education, and public safety—all key to rural population growth. The benefits that some rural communities are already experiencing will only be possible for all if robust broadband is available, affordable and sustainable. Rural telecom providers and lenders such as RUS must have regulatory certainty before they can make greater investments in the networks of the future. One important key to regulatory certainty is a broadband-oriented support mechanism for small, rate-of-return carriers that gives rural consumers options in selecting the services that best fit their needs on the networks that the mechanism helps to enable and sustain.

Senator MORAN. Thank you very much.

Mr. Chrisman, before you testify, let me recognize the Senator from Oregon, Senator Merkley.

Senator MERKLEY. I am delighted that Mr. Chrisman has been able to come and share his experience, and to be accompanied by his wife, Julie.

Mr. Chrisman is from Enterprise, Oregon. Along with his brother, Doug, he has been working to provide affordable housing to Oregonians for 25 years. They have developed over 50 affordable housing projects and manage an additional 50, serving more than 3,000 households across rural Oregon and Washington. Their business employs about 200 people.

Mr. Chrisman is a valuable and successful user of Rural Development programs, specifically multifamily housing programs and USDA’s rental assistance program. His insight and experience from the frontline will point to a substantial challenge that we have right now that needs to be addressed urgently.

I am so delighted you could come and share your testimony.

Senator MORAN. Mr. Chrisman.

<sup>7</sup> See H.R. 5828 § 102(a), 111th Cong., 2d Sess. (2010).

**STATEMENT OF TONY CHRISMAN, VICE PRESIDENT AND OWNER,  
CHRISMAN DEVELOPMENT INC.**

Mr. CHRISMAN. Thank you. Good morning, Chairman Moran, Ranking Member Merkley. My name is Tony Chrisman. I am a rural housing developer and property manager from Enterprise, Oregon.

It is pretty interesting to hear all the stories about rural America. The town I live in does not even have a stoplight. But we have been able to develop a business even in that small community.

It is an honor to appear before you today to discuss the urgent situation involving the USDA Rural Development Multifamily Housing Rental Assistance Program. My company has developed, owned, and managed affordable housing complexes for 26 years. We developed over 50 affordable housing projects and manage an additional 50 projects, representing over 3,000 households across Oregon and Washington. We have 200 employees.

Seventy-five percent of the projects that we own and manage have been funded through the USDA Rural Development Multifamily Housing Program and receive project-based rental assistance directly from USDA Rural Development. That is the payment that is made on behalf of the low-income tenants, which pays part or all of their monthly rent and utilities.

I am here to bring your attention to the current crisis that has occurred. This summer, we were alerted to the fact that the rental assistance program faced a shortfall of funding due to language that was included in the Consolidated and Further Continuing Appropriations Act of 2015. We received one notice in the mail from Rural Development that one of the projects we manage would no longer be receiving rental assistance for the next 5 months.

We were very concerned about that. We began doing additional research and realized the balance of our Rural Development properties were also going to be affected.

What we discovered was alarming. Due to a change apparently requested by USDA Rural Development, rental assistance contracts could no longer be renewed as they had been in previous years. In addition, due to the fact that USDA RD budgeted each project's rental assistance based on a statewide average and not their actual use, any project with a higher than statewide average of rental assistance faced a shortfall.

In August of this year, Rural Development failed to provide rental assistance to many of our properties. As of last Friday, 17 projects representing 770 low-income households have not received rental assistance for at least 1 month. The amount of rental assistance not paid to date is \$365,000.

For a small company such as ours, the consequences of this situation could bring an end to our business. We received no official notice or any indication from Rural Development that payments would not be made with one exception. These payments generally represent about 80 percent of the monthly revenue for each affected property.

We have no idea when payments may resume. Unfortunately, just listening to Administrator Hernandez, it appears that they still have not decided whether they are going to pay the back payments or not, even after the continuing resolution.

We are left in a no-win situation with low-income tenants who are unable to afford their rent and Rural Development unwilling or unable to pay rental assistance on their behalf.

What is happening with our company and tenants is playing out across the country. There are 272,000 units of affordable housing and 14,900 properties across the United States that receive Rural Development rental assistance.

We have talked to other affordable housing owners and managers across the country and discovered they are experiencing the same thing, and payments of rental assistance are not being made. Many owners and managers of these properties were giving the low-income tenants notice that they need to pay much higher rents as a result of rental assistance not being paid on their behalf.

If this situation is not remedied, significant impacts will occur. First, without regular rental assistance payments, most tenants cannot afford the full rent on their own. As a result, they face displacement and possibly homelessness. The average income of our portfolio of the tenants who receive rental assistance is approximately \$10,000. The average household income of the families who live in the USDA Rural Development properties is extremely low, and these tenants represent some of the most vulnerable members of our society.

The way USDA Rural Development has dealt with this matter will result in tenants with the lowest incomes and greatest needs being displaced from housing that many of them have lived in for years.

Second, the 14,900 existing USDA-funded properties across the country will face foreclosure, bankruptcy, and possibly default on their financial obligations.

The third consequence of the situation is that many jobs across rural America will be in jeopardy as these projects fail and managers, contractors, and support staff are terminated.

I am here today to ask for your help to resolve this situation. Thank you.

[The statement follows:]

#### PREPARED STATEMENT OF TONY CHRISMAN

Good morning, Chairman Moran, Ranking Member Merkley, and distinguished Members of the Subcommittee. My name is Tony Chrisman and I am a Rural Housing Developer and Property Manager from Enterprise, Oregon. It is an honor to appear before you today to discuss an urgent situation involving the USDA Rural Development Multifamily Housing Rental Assistance Program.

My companies have developed, owned, and managed affordable housing complexes for 26 years. We have developed over 50 affordable housing projects and manage an additional 50 projects representing over 3000 households across rural Oregon and Washington. We currently employ approximately 200 people.

75 percent of our housing projects have been funded through USDA Rural Development multifamily housing programs and receive Project Based Rental Assistance directly from USDA Rural Development. Rental Assistance is a payment made on behalf of low income tenants which pays part or all of their monthly rent and utilities based upon the tenants' income.

I am here to bring your attention to the current crisis that has occurred in the USDA Rental Assistance program. This summer, we were alerted to the fact that the Rental Assistance Program faced a shortfall in funding due to new language that was included in the "Consolidated and Further Continuing Appropriations Act, 2015." We received a single notice from USDA Rural Development that one project we managed was going to run out of Rental Assistance in 30 days and would not be eligible for further payments for 5 months. We were very concerned. We began

doing additional research on the balance of our USDA Rural Development properties to determine if other projects would be affected. What we discovered was alarming. Due to a change, apparently requested by USDA Rural Development, in the language of the "Consolidated and Further Continuing Appropriations Act, 2015" Rental Assistance contracts could no longer be renewed as they had been in previous years. In addition, due to the fact that USDA RD budgeted each project's Rental Assistance based upon a state-wide average and not their actual budgets, any projects which had higher than the state-wide average of Rental Assistance faced a shortage.

In August of this year, USDA Rural Development failed to provide Rental Assistance to many of our properties. As of October 15, our companies have 17 projects representing 770 low income households that have not received Rental Assistance for at least 1 month. The amount of the Rental Assistance not paid to date is \$365,000. For a small companies such as ours, the consequences of this situation could bring an end to our business. We received no official notice or any indication from USDA Rural Development that payments would not be made with one exception. These payments generally represent about 80 percent of the total monthly revenue for each affected property.

We have no idea when payments may resume and if payments will be made in arrears. Virtually no communication has been forthcoming from USDA Rural Development. We are left in a no win situation with tenants who are unable to afford their rent and USDA Rural Development unwilling or unable to pay rental assistance on their behalf.

What is happening with our companies and tenants is playing out in other parts of the country right now. USDA RD Rental Assistance supports 272,322 units of affordable housing in 14,900 properties across the United States. We have talked to other affordable housing owners and managers across the country and have discovered that they are experiencing the same thing and payments of Rental Assistance are not being made. Many owners and managers of these properties have given the low income tenants notice that they need to pay the much higher rents that result from the USDA Rental Assistance not being paid on their behalf. Several newspapers across rural America have documented that low income tenants are now being asked that their portion of the rent increase dramatically.

If this situation is not remedied significant impacts will occur. First, without regular Rental Assistance payments, most tenants cannot afford the full rent on their own and as a result, they face being displaced and possibly homeless. The average household income in our portfolio is less than \$10,000 per year. The average household incomes of the families that live in USDA Rural Development properties is extremely low and these tenants represent some of the most vulnerable members of our society. The way USDA Rural Development has dealt with this matter will result in tenants with the lowest incomes and the greatest needs being displaced from housing that many of them have lived in for years.

Second, the 14,900 existing USDA funded properties across the country will face foreclosure, bankruptcy, and will default on their financial obligations. In our case, since many of our projects have been funded with Federal Low Income Housing Tax Credits and additional funding sources such as State low income housing loans and commercial loans, serious financial outcomes will result.

Our companies' business has primarily been to preserve older affordable housing projects by acquiring the properties and using a multitude of State and Federal funding mechanisms to recapitalize, rehabilitate, and preserve the properties in order to keep the valuable federally funded rental assistance. The state of Oregon and Washington have funded and invested in numerous projects specifically to preserve projects like these across rural areas. The shortage of Rental Assistance puts all of this work at risk. State and Commercial financing will dry up if the availability of the Rental Assistance is lost. Banks and Investors will stop investing in the low income housing tax credits that have been used to fund these properties. Losses will be large.

Finally, the third consequence of this situation is that many jobs across rural America will be in jeopardy as these projects fail and the managers, contractors, and support staff will be terminated.

It is our understanding that several things need to happen to in order to remedy this current situation.

First, language limiting the ability of USDA Rural Development to renew contracts only once a year must be removed from next year's budget. The recently passed Continuing Resolution addresses this issue until December, but unfortunately it does not deal with the longer term issue. We need this language removed from future budgets.

Second, according to industry groups, it appears that the USDA RD Rental Assistance Budget is not sufficient to meet the requirements of the program. Although the USDA has repeatedly insisted that their budget was sufficient, it clearly was not sufficient and USDA ran out of rental assistance funds this past summer for many projects. Industry groups believe the budget is short by approximately \$220 million. USDA Rural Development has not been forthcoming about the exact amount of the shortfall.

There are numerous other proposals that could make this program more effective and return the focus to managing the properties and supplying housing for low income rural families. However, if the current Rental Assistance Crisis is not fixed none of these proposals will matter.

Thank you for allowing me to testify and I look forward to answering any questions you might have.

Senator MORAN. Mr. Chrisman, thank you very much.

I thank all of our panel. We are going to take some time now and have a conversation and ask you questions and solicit your answers.

I would start with you, Mr. Chrisman. You heard the conversation earlier between Senator Merkley and Rural Development, between me and Rural Development. I would indicate that today's hearing is the first indication that we have had from Rural Development that the language that was included in the omnibus bill, the legislation that you described, was insufficient to backfill the rental assistance.

We will continue to press Rural Development for more clarity, because we believe they have the authority to do what needs to be done. It does not solve the problem permanently, but it certainly solves the immediate problem. We will continue our efforts, and I look forward to working with your Senator, Senator Merkley, in that regard.

What is the authority by which tenants can be required to pay additional rent in this circumstance? Is that carte blanche? Are there restrictions? One, I understand the financial circumstances that most if not all of those tenants are in, so it is not a practical solution. But what is the legal ability to raise rents in the absence of the rental assistance?

Mr. CHRISMAN. In our portfolio, our lease agreement specifically lays out, if Rural Development does not pay the tenant's portion of the rent, it is not really a rent increase. The rents are set by Rural Development, and then they pay a certain percentage of the rent. So we would just go to our lease agreement. When the rental assistance payments stop, we are allowed to raise the rent to the level that the rent is set at with the difference.

Senator MORAN. So you have the legal ability under your rental agreement to raise the rents. You do not have an ability to actually accomplish those increased rents being paid.

Mr. CHRISMAN. The reality is most of the tenants could not pay them even if you raised the rent on them. So what do you do? We have been in the business of serving this population for 25 years. Now we are in a situation where, no matter what happens, we are going to make the wrong decision. Tenant advocates will sue us if we start charging them the additional rent. The tenants, if we do evict them, because that is really where you are going with this, they have no other place to turn.

Senator MORAN. Are your rental agreements approved in advance by USDA?

Mr. CHRISMAN. They are.

Senator MORAN. So the authority that you described, the legal authority that you described, an ability to raise the rent in the absence of rental assistance, is something that USDA has approved in your rental agreement?

Mr. CHRISMAN. That is right.

Senator MORAN. Okay. I would tell you, Mr. Chrisman, in Kansas, the most common conversation I have with a Chamber of Commerce executive, an economic developer, a mayor, a city councilmember, when you are visiting a community and you want to talk about what is going on in the community, almost without exception the conversation turns to lack of housing.

Do you avail yourself, does your company avail yourself to programs outside Rural Development, outside USDA? Are you involved in the Department of Housing and Urban Development (HUD) programs or others? And can you tell me, the Rural Development programs, why they are useful to you? What the problems are? Is there someplace else you could go that would be a better source of assistance to accomplish the goal of housing for low-income people across the country, in particular rural America?

Mr. CHRISMAN. We use the HUD programs, low-income housing tax credit programs. But the unique characteristic of the Rural Development program is the portfolio of properties that were built in the 1970s and 1980s that have the rental assistance, there is just no substitute for that. These serve the lowest income families and the most needy people in our whole communities.

I would say most of our properties are probably 25 percent chronically mentally ill tenants who have no alternative. They get a disability payment and that is their only option. So there is no substitute for these programs because rental assistance does not exist in any other format except the Rural Development program.

Senator MORAN. Thank you.

My time has expired. We will have another round.

Senator Merkley.

Senator MERKLEY. I want to continue this conversation, because this is so important.

During the more than 2.5 decades that you have been involved, has there been another situation, another year, when suddenly you were at the end of the fiscal year and payments were going to stop?

Mr. CHRISMAN. This has never happened in the Rural Development program. There was a short period during the sequestration when there was a question. But in that situation, Rural Development was notifying us, telling us what was going on. We have never had a situation where we did not receive any notice.

I mean, you can imagine running a business, you have lawn mowers and people working at the project, and you get no notice and you have no rent. Eighty percent of the revenue for that month does not come in.

Senator MERKLEY. So even though there is a clause in the contract that says, if Rural Development stops paying, the tenant is responsible for the full amount of the rent, no one anticipated that clause would ever have to be used. In fact, no one would think that it could be used because these tenants could not possibly pay the full rent.

Mr. CHRISMAN. That is right.

Senator MERKLEY. So now you are in this difficult situation. Different owners have probably taken different approaches. At this point, have you notified tenants that they are responsible for the full rent? Are you holding out for us to get a successful response from Rural Development to backfill the hole?

Mr. CHRISMAN. We have not notified the tenants. We spent a lot of time talking about it. But these are the people who we have been serving for 25 years. These are mothers of people I went to high school with, friends I went to high school with. I know a lot of the tenants. I just cannot see us doing it, unless it is the very darkest end.

We thought the continuing resolution had temporarily resolved it, but the testimony I just heard sounds like that may not be the case. So some of these projects that have shortages, it looks like, according to Administrator Hernandez, may not be getting paid.

So I am a little frustrated to hear that.

Senator MERKLEY. I am so glad you are here. Because of this hearing, we learned for the first time today that the language that we worked out with bipartisan staff involved, with Rural Development involved, signing off on the language, that they have some legal concern, a legal concern that we have not heard the details of. We did not know until today that they had run into an obstacle here.

We are going to push very hard to get to the bottom of it.

If you were to follow the contract and ask for the full rent and your tenants would not then would not be able to pay it, then there is just no good answer. An eviction results in homelessness. As you put it, there is no option. We would be putting people into the street across rural America, because there are thousands of projects involved here. That is just unacceptable.

You are nodding your head. I will just record that for the record.

Mr. CHRISMAN. Yes.

You are telling me things I have been thinking about all summer. It is a very frustrating situation to be in.

Senator MERKLEY. There are clearly changes in the way that this program was administered internally that led to this as well. And when I say that, you refer in your testimony to the fact that the projects were assigned an average. Any project, any multifamily housing complex that has very low-income tenants who are below the average, then that average is going to result in a shortfall at the end of the year.

Then we have the bigger issue of the missed estimate for what the program would cost across America. That is the \$110 million or so shortfall or \$100 million shortfall that we referred to earlier.

So we are going to push very, very hard to get this program backfilled and to resolve the issue for this coming year, so that we are not in this situation come August or July of next year. The estimates that we have show an even larger deficit.

So I think there are mechanics that have to be fixed in the way that funds are assigned to individual projects, and an overall deficit that has to be addressed. My hope is that common sense will quickly prevail and that we will get to the bottom of this. We have been trying to. We thought we had.

Let me just say, this is a 100-percent absolutely unacceptable way to treat the owners of these complexes who are administering these in partnership with the U.S. Government. But it is absolutely unacceptable that the tenants be on the receiving end of these missteps.

So thank you so much for shedding a personal spotlight on the problem. I think it will have helped a great deal that we have had this conversation in public today.

Mr. CHRISMAN. Yes. It is my pleasure to be here.

Can I respond?

Senator MORAN. You may.

Mr. CHRISMAN. It is hard for me to believe that the agency cannot calculate the amount of rental assistance. This program is a very stable program. I mean, I am terrible at math, but I think I could do it.

The fact that they could be off by hundreds of millions of dollars, listening to that was just unbelievable to me.

Senator MORAN. Thank you for responding. I share the same sentiments. We have never been officially notified of a shortfall to begin with. We have never been notified that the language in the continuing resolution designed to temporarily resolve this issue is insufficient. And only, again, today did I learn that there is no capability of telling us what that number is.

So thank you for your testimony. We are glad we had this hearing so that we now know this. Although I would assume we would begin hearing from you and others in your circumstance as your representatives. This would not have been something that would go on much longer.

My impression is from your testimony is you were expecting this problem to be resolved. You have not taken the effort to try to collect money from tenants. You apparently had not notified Washington, DC, us, of a problem because you assumed that was being taken care of.

Mr. CHRISMAN. Well, we have actually been contacting Washington, DC, all summer because once we found out there was a shortage, we were so shocked, because for all these years, the budgets that you get may be inaccurate, but the rental assistance has always been paid. So we did not really believe it until the first payments just stopped.

Like I said, 17 properties, only one of them received any written notice or anyone at RD telling us that there is no rental assistance.

Senator MORAN. Tell me again, those payments stopped when?

Mr. CHRISMAN. In August.

Senator MORAN. August.

Mr. CHRISMAN. We have a whole bunch more properties, and it's our calculation they are just going to keep on stacking up until about 75 percent of our Rural Development portfolio will not be getting payments.

Senator MORAN. Thank you very much.

Mr. Boisvert, does Wilson, Kansas, have a stoplight?

Mr. BOISVERT. No, we do not.

Senator MORAN. I just want to make sure that we were not out-Kansaned the gentleman from Oregon.

Senator MORAN. There has always been an excess, Mr. Boisvert, in the demand for RUS telecommunication loan programs. There has always been more demand than dollars available. But that is not so true anymore.

Recently, I would say in the last 3 years, the demand for RUS loans no longer exceeds the supply. I wonder if you could explain why that is.

My impression would be the uncertainty that your company or others in similar circumstances face, not knowing what the Universal Service Fund requirements are going to be, what revenue is going to be generated from that fund for your company and others, means that there is less demand for the loan program at RUS.

Does that assumption have any validity?

Mr. BOISVERT. Mr. Chairman, yes, it does. I think we would see that demand correlate to the 2011 FCC order on the Universal Service Fund.

As you know, when we take out RUS loans, those are long-term loans. Those are done with a certain understanding of what is in place for universal service, consumer rates, all the things that a company would use to operate and repay its debt.

So when the order came out, a great amount of uncertainty did occur with the changes that were there. As I mentioned in my comments, the new mechanism known as Connect America Fund, or CAF, there is still not one for the rate-of-return part of the industry, which Wilson is part of.

So clearly, I think the demand is still there. If you look at rural companies, we are in probably one of three phases of building out our networks to bring broadband to rural Kansans and others across the country. They are built with debt to repay and costs operate. They are partially built, which is our case. But I have not felt comfortable completing the build. And there are those who have yet make that next step in the investment but want to and plan to, as soon as certainty does resume with universal service.

Senator MORAN. Maybe a way of saying what I was attempting to ask is not that there is less demand, but there are less applications for that money, waiting for certainty to arrive, similar to Mr. Chrisman waiting for certainty to occur.

The point I would make, and ask you to agree or disagree, is I often think of this issue of the order of 2011 as an impediment toward a telephone company's ability to repay loans that already are in existence to RUS. So less revenue means that our ability to repay the loan is diminished. What you just said reminds me of another aspect of this. With that uncertainty or the belief that there is going to be less revenue coming following the order of 2011, there are areas of the country in which the desire to serve still exists. But the ability, the uncertainty of whether or not there is going to be the revenue, diminishes the chances.

So initially, I thought the topic of this hearing in part would be about whether or not a phone company has the ability to repay an existing loan. There is another damaging aspect of FCC decisions, which is that we may not even ask for the loan because of either the uncertainty or the revenue stream is insufficient, which means a significant number—I do not know what it is—hundreds, thou-

sands of people across Kansas and across the country will have less ability to access broadband.

Does that make sense to you?

Mr. BOISVERT. Yes, it does, Mr. Chairman. I would agree with your assessment.

Without that predictable and sufficient and sustainable universal service, that demand may not materialize in the form of taking our infrastructure loans to bring broadband to rural Kansans.

Senator MORAN. You indicated, in your company's circumstance, that has occurred on two or three exchanges in which you were prepared to borrow money to expand broadband but as a result of that order have not made that loan application?

Mr. BOISVERT. I actually have the loan but I have not drawn the funds, resulting in the same thing. That is correct.

Senator MORAN. Okay. Now, the order was modified, the FCC modified their original 2011 order. Did that make a difference in the types of issues that we are discussing today?

Mr. BOISVERT. Well, there have been seven orders on reconsideration since the original order. There was a good step forward in removing one of the formulas that was very troublesome. But as we speak, we still do not have resolution to that. So the work is not done.

I know the industry and the National Telecommunications Cooperative Association (NTCA), which we are part of, are working very hard with FCC to come to a truly workable, sustainable Universal Service Fund that will allow this work to continue.

Senator MORAN. The topic of today's hearing is Rural Development. The concerns that you and I are talking about may be more directed at the FCC than Rural Development, but the consequences exist to Rural Development's ability to either have their loans repaid or the demand necessary to provide more money to expand broadband in rural America.

Mr. BOISVERT. There is clearly a connection, yes.

Senator MORAN. Let me turn to others. Now that we are down to just me, we may have a series of rounds of questions.

I will go back to you, Brian. Is there any indication of when that certainty may become known? When does this problem go away? Or is it just with us for the foreseeable future?

Mr. BOISVERT. We hope there is an end.

And we do thank this subcommittee and others for reaching out to the FCC to talk about the standalone broadband. All five commissioners I believe have made the commitment to resolve this by the end of the year. That is rapidly approaching. So I am still hopeful that a resolution can be made.

But as part of the industry and the association, as we work toward this, it is really important that, essentially, we get it right. This is a long-term solution that we are seeking, not just trying to hit a deadline. So it really is important to us to stay at the table to work to make sure that all things are tried.

So if there is a potential recommendation to go to a certain method, we want to make sure there is an opportunity for everybody to work that method to make sure it is sustainable and provides the resources that are needed for rural Kansans.

Senator MORAN. Do you have any sense that Rural Development is advocating for a position beneficial to the repayment of their loans and to the continued expansion of broadband availability with the FCC?

Mr. BOISVERT. I am not personally aware of conversations. I do believe they are very supportive. They have a large portfolio out there that could be at risk. They are a great organization to work with, the RUS. So I believe they, certainly, would like to see a successful resolution to this as well.

Senator MORAN. Thank you.

Mr. Lowry, your testimony focused significantly on REDLG. I just want to ask you the broad question, is there any proposal, any suggestions of needed changes to the program? Or are you satisfied with the way it works and the way it is administered?

Mr. LOWRY. Overall, I think that there is satisfaction with the way the program is working. There is a proposal for a \$1 million limit on individual loans, which would make more loan funds available to more people. We think that is a positive change. But overall, we are satisfied with the program.

Senator MORAN. Do you know what the average loan amount is?

Mr. LOWRY. I do not, but we can get that information and pass it on to you.

Senator MORAN. We talked a bit and you talked about environmental or endangered species issues that impact the bottom line of a utility company. You might highlight, and I am reluctant to raise this topic because for a few days here I was known as the lesser prairie chicken Senator, but you might highlight for me, for my benefit and for the record, the consequences of the listing as a threatened species to your company or to utilities in Kansas or the region. That is five States, generally.

Mr. LOWRY. Within the context of this hearing, what it essentially does is undermine the good work that RUS Rural Development is doing. Those programs are all about making services to rural residents affordable. When you have a regulatory initiative, the lesser prairie chicken being a good example, that layers additional costs on the service providers, say an electric service provider, that impacts affordability.

So the needle moves in one direction with RUS program; it moves in the other direction in a negative way with initiatives such as the lesser prairie chicken initiative.

To that initiative specifically, there are proposals that line construction be completed underground. Underground construction adds, in some cases, a tenfold cost to the construction of electric facilities. Those costs can only be recovered from ratepayers.

So again, you are taking what would otherwise be an affordable service and you are impacting that affordability by requiring compliance with regulations that have, in most cases, dubious benefits.

Senator MORAN. This issue of the lesser prairie chicken or endangered species, and now the more recent clean power plan, what is wrong with those whose suggestion is just have the utility companies raise the rates?

Mr. LOWRY. Well, we see all the time that the two primary drivers for an electric customer will be reliability and price. We know, as was said earlier in this hearing, that the cost of electricity is a

key driver in determining where people locate their business. So yes, you can have the price of electricity go up. There will be some people, a household, who won't not find that objectionable. But business and industry will find it as a driving factor in their decision about where they locate. It affects their overall profitability.

Senator MORAN. I suppose, in a broad sense, today's hearing is about rural development. I would suggest that our ability to attract and retain business, manufacturing and others, to rural America is in part determined by utility rates. Is that fair?

Mr. LOWRY. That is a fair statement. You know, the customer density in rural America is much, much lower than it is in urban America, meaning we have fewer consumers per mile of line from which we can recover our costs than do our city brethren. So additional costs recovered from a much, much smaller pool of ratepayers means higher rates for those ratepayers. That is a big concern of ours.

Senator MORAN. A point I would make is that while you testify about the value of the REDLG program, which would be assistance to an individual, generally small business and its location or expansion in your consumers' territory, if your rates are significantly higher than other utilities, businesses will make decisions about where to locate.

So your REDLG is important in the micro sense, but what your rates are is important in the macro sense to rural America.

Mr. LOWRY. You are undermining the benefit of the REDLG program with other policies that would increase electric costs.

Senator MORAN. Let me ask specifically the consequences to Rural Development and their loan portfolio. Does that loan just get paid? Regardless of the regulatory environment in which you operate, you are required to pay the loan to RUS, right?

Mr. LOWRY. Are you talking about on the electric side?

Senator MORAN. Yes, on the electric side.

Mr. LOWRY. Yes. RUS borrowers borrow money to complete projects and construction work plans. The clean power plan is a good example where you are making investments that are decades long investments, and they are enormously expensive. When you have a regulatory initiative that essentially says, for example, we will generate less if at all from a coal resource and instead we will generate more from some other resource.

Well, at the start, you have a power plan. And if EPA, through the clean power plan, essentially says you cannot utilize that power plan, then you have to have a second power plan to provide service. So the ratepayer, instead of paying for one plant, is now paying for two.

The loans do not go away. They are still going to be due and owing.

So when you hear the term "stranded investment" used in the context of clean power plan, that is one element of stranded investment. You have an asset that you cannot utilize.

Senator MORAN. So RUS made a loan to a utility company expecting the life—they loaned the money to build a power plant or to improve a power plant. They expected the life of that plant or its improvements to be a certain amount of time. And potential changes that are now on the horizon would mean that the value

of that plant is diminished. So the asset for which they have made the loan is diminished in its value, and the revenue that it will generate to repay the loan is less.

Mr. LOWRY. That is true.

Senator MORAN. Okay. And that does not affect necessarily the portfolio of RUS until there are defaults. Is that true?

Mr. LOWRY. Yes, that would be true. They are going to expect repayment, as they should. But the ability to repay is going to be hampered.

Senator MORAN. A utility company cannot renegotiate their loan with RUS based upon changing circumstances of a new clean power plan. Is that right?

Mr. LOWRY. Well, that probably remains to be seen. There is no requirement that RUS renegotiate loans. So it would be another example of a regulatory uncertainty.

Senator MORAN. Just for the same reason that there is assistance to utility companies serving rural America, that is because the ability to get a return necessary to build the plant and provide the service is less, that would mean that any changes in the economic circumstances surrounding that plant is all the more important because it already is so fragile, so marginal to begin with.

We would not be making loans to rural America if it was easy to get a sufficient return on investment in utilities. We make those loans because it is difficult. And the change, therefore, would be the most damaging or dramatic in a rural setting. Does that make sense?

Mr. LOWRY. Yes, that does make sense. Again, it goes back to customer density. It is all about the taxpayer or, in our case, the ratepayer. We have fewer of those in rural America than our city brethren. So it is a more fragile environment.

Senator MORAN. I co-chair a caucus in the Senate with one of my Democrat colleagues. It is about competitiveness. It is about reintroducing additional manufacturing opportunities to the country, not just in rural America. But I would tell you, in so many circumstances in which you look at a reason a company has brought their employees home, bringing more manufacturing jobs back to the United States, has had a significant amount to with the cost of utilities. If you can provide the utility structure, including water, at a rate that is more affordable, the chances of manufacturing returning to the U.S. from someplace abroad is enhanced.

Then you add that to we can never afford to have a competitive disadvantage in the territory that you serve.

Mr. LOWRY. Yes.

Senator MORAN. Mr. Simpson, the way I look at this, kind of related to this environmental issue, is that there are lots of rules and regulations involving the quality of water, rightfully so. We want clean water. I represent lots of communities in which there are not enough ratepayers. You cannot raise the water rates sufficient to raise the money necessary to comply with regulations.

One comes to mind. There are 99 ratepayers in the community, but they have these standards they have to meet. They cannot raise the rates on 99 people to get the money necessary to accomplish the requirements, to accomplish the goal of that standard for clean water.

Therefore, the programs that help a community become even more important, again, in rural America because you cannot finance it with the people who are paying their water bills each month.

I assume that that is, in a sense, your mission, how we help people who cannot afford to do all the things that need to be done to provide clean water in a sufficient quantity.

What works? What is the most important thing to you?

Mr. SIMPSON. I think the Rural Utilities Service with right now the historically low interest rates, even with the 40-year term, when it is coupled with the grant portion, it can make it affordable.

You are right, Mr. Chairman, a lot of these small communities, you are looking at a little trailer park. In my home State, they do not meet the capacity. Or the unpaid mayor you have to go find at his real job in the casino——

Senator MORAN. We have no casinos in Kansas. That is almost true. Not exactly.

Mr. SIMPSON. They do not have the capacity and the resources to hire someone to operate the system. A lot of times, you will have a part-time person that does several systems.

That is where our folks that have this vast amount of experience being former water operators and training with all the certifications can come in and fill that void for these communities that simply do not have the expertise and cannot afford it.

But we think that Rural Development program with that grant component is very unique and can make it so these low-income communities can have affordable, clean water.

Senator MORAN. I know the National Rural Water Association well enough to know that I assume that your request would be additional dollars put into those programs. That is a standard reply that we would get in this subcommittee or to me as a member of the Senate.

But I would ask you, are there program efficiencies, program management, in addition to more money, are there ways that we can formulate the programs to work better?

Mr. SIMPSON. Yes, sir, Mr. Chairman.

First of all, we are very appreciative to the Senate mark for our programs. It was very gracious.

Senator MORAN. I was fishing for a compliment. Thank you.

Mr. SIMPSON. You are right. I think I have to give former Under Secretary and Administrator McBride credit. They have done something pretty smart called RD Apply, which is really bring in Rural Utilities Service into the modern century as far as IT and technology is concerned, where, literally, you can take a smart phone, your iPhone, a laptop, and you can access their application process.

They trained our folks a couple weeks ago in Oklahoma City. It was honestly very easy.

And another thing, why this is so good, you heard about delays from RUS and the inconsistency with some of the programs, the staff that got reduced during the last 5 years. It is transparent and accountable, too. So you know your water specialists, the program director, the State director, everybody can see this process. I think that that is a smart way that they are going ahead to use easy, off-the-shelf technology to do the program more efficiently.

Senator MORAN. Thank you.

There is at least talk about the existing water and waste disposal loan program involved in a portfolio sale.

Mr. SIMPSON. Yes, sir.

Senator MORAN. Anything that I should know about that? I would guess we will have some specific questions to address to you in writing.

Mr. SIMPSON. Yes, sir. Let me be clear. A lot of what I am basing my response on, I do not have anything in writing from the Department. I have had some conversations. We would be delighted to review or comment or add our suggestions.

Yes, there have been several ideas about how you bring the private sector in to complement the Rural Development mission with their limited loan and grant dollars. We are for that. We think that the guarantee program that is not very utilized, only made a handful of guarantees last year, the private sector can play an important role there, especially for communities that have more capacity and resources to debt service a private-sector loan.

That said, we do have some concerns. There are discussions about doing a partial prepayment or participating loan to where a utility in Kansas that has this 40-year loan, they are in year 20 and the private sector can come in and pre-pay 50 percent of that outstanding balance to the Treasury. I would imagine the private sector is going to look at that value, what they think it is worth, and how the Treasury is going to look at it, because you are cutting off that stream of payment for the remaining 20 years, with the interest. And then the utility in Kansas, for example, would still make their standard payment. Nothing would change. They are making a \$10,000 or whatever it is monthly payment. But half of that would be diverted to the private entity, the investor.

I cannot understand the public policy of that. It does not benefit the utility. It does not impact the end-user. I do not understand that thought process.

We have some concerns with that. Also, we would want our utility bar common with rural folks and how they operate business to have knowledge about their loans being modified, to have the right to say we have to check off on it or the right for first refusal. If there is a concern about some of the loans that are 20 years old or longer, that they are paying a higher interest rate, you might want to look what this subcommittee did before as an option, the 502 guarantee program, when you established a separate refinancing category for the 502 guarantee program, which was at a cheaper subsidy rate to give these existing rural utility bars the opportunity to refinance if the direct loan rate was lower. It was a benefit for the business model.

That I think would be a better policy because it would lower the rate for the utility so you free up some money to do some deferred maintenance and not pass on the cost to the user.

So, yes, sir. We do have some concerns about the public policy benefit of an action like a partial prepaid loan.

Senator MORAN. Water utilities have access to funds besides Rural Development in what ways? The public financing of water infrastructure, going to the bond market and the utility issuing rev-

enue bonds to be repaid from the revenue of sale of water and treatment of wastewater?

Mr. SIMPSON. Yes, sir. A lot of them are municipalities, quasi-governmental entities. They have a wide variety. A lot of them will use the SRF, the EPA revolving loan fund. That varies from State to State how they administer it.

A lot of them will use bond money. Our Kentucky entity has their own bank, basically. There is a wide variety of different programs they could use. The guarantee program, in my opinion, has not been utilized very often.

Senator MORAN. So the two options that a water utility in Kansas would have would be Rural Development and the EPA, as far as public sources of support?

Mr. SIMPSON. Yes, sir.

Senator MORAN. Okay.

I appreciate your comments in regard to the nature of Congress working in a bipartisan effort. I would use this as an opportunity to highlight that the Agriculture Appropriations Subcommittee report was passed by the full committee 28-2, the best of any appropriation bill that worked its way through subcommittee and into the full committee.

We welcome you back to the subcommittee. I suppose it is significantly unusual for the circumstance to have come full circle and you are on that side of the table.

Mr. SIMPSON. Yes, sir.

Senator MORAN. We are glad to have you, and we appreciate your expertise.

I think we are about ready to conclude. I would just ask any of the witnesses if they have a point, an issue, that they wanted to make certain that they clarify, raise, something they want us to know before we close the hearing?

Mr. BOISVERT. Mr. Chairman, I want to thank you for this opportunity. I never want to lose sight, and we don't, that, in the end, we want to keep consumer rates reasonable and provide this opportunity for every rural Kansan and every rural American. So that is why we work as hard as we do to do the things we do. It is for that benefit, to keep our country connected. There is so much benefit to be gained from the rural-urban connection and very much a focus of that are consumer rates. Thank you.

Senator MORAN. Never wanting to have somebody have the last word but me, I would say, I intended to ask you this earlier, in the absence of Wilson Telephone Company, what difference does it make to the people who you serve?

Mr. BOISVERT. Well, I would like to believe we make a lot of difference. We are very much a part of the community. Not only do we provide state-of-the-art communication services, but we also are members of the community. We live where we work. We support our youth. We do scholarships.

Getting those millennials to come back to rural Kansas is very much a priority. We think with some of the modern networks and the services that they offer and the opportunities that they offer, we hope this will be appealing, and once the younger generation goes off to college, that they will return back home to help on the family farms, to start new businesses, to create new opportunities.

We think that is part of it. That is part of what we try to do as well.

Senator MORAN. Mr. Boisvert, is it safe to say that, in the absence of a company like yours and those telephone companies similar to yours across the country, that the services that you provide would not be provided or would not be provided at a rate that was affordable?

Mr. BOISVERT. I would agree with that. That is really how these companies came to be in the first place. The market is not there that the large companies are going to enter into. We are very rural, very low population density. So I do fear that if these companies were not there, that void would not be filled.

Senator MORAN. Thank you.

Anyone else?

I appreciate your testimony. Thank you for joining us today. I consider it an informative hearing, and it is because of your willingness to come and talk to us today.

#### ADDITIONAL COMMITTEE QUESTIONS

Senator MORAN. For my colleagues on the subcommittee, any question that they would like to submit for the hearing record should be turned into our subcommittee staff within 1 week, which is Wednesday, October 28.

If a question is directed to you or to Rural Development, we would appreciate if we could have a response back within 4 weeks.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

#### QUESTIONS SUBMITTED TO HON. LISA MENSAH

#### QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

##### SECTION 515 RURAL RENTAL HOUSING

*Question.* A 2004 USDA report (Rural Rental Housing Comprehensive Property Assessment and Portfolio Analysis) indicated a 20 year \$2.6 billion cost to maintain the section 515 rural rental housing portfolio.

We are 10 years into that timeframe, how much progress has been made?

*Answer.* Rural Development has been actively engaged in the preservation of its Section 515 portfolio, but more work needs to be done. As a result of the 2004 Comprehensive Property Assessment, Congress authorized a demonstration program through annual appropriations language providing RD with more flexible tools to encourage the revitalization of its Section 515 and Farm Labor Housing properties. The demonstration program is known as the Multi-Family Preservation and Revitalization program (MPR). Through the end of fiscal year 2015, RD has obligated \$1.051 billion for the rehabilitation of 982 properties and more than 33,000 units of affordable housing. MPR has also facilitated a high level of cooperation with state housing finance authorities by leveraging billions of dollars in tax credits to stretch our limited appropriation dollars.

In order to continue making progress in our revitalization efforts, RD has requested that Congress authorize the MPR program permanently. If the program was permanently authorized, the Agency could create regulations to institutionalize the program's benefits and signal to potential program participants that both the Executive and Legislative branches of the Federal government are committed to the revitalization of our affordable housing.

*Question.* What improvements have you made in procedures or regulations to ensure that these housing developments are in adequate condition?

*Answer.* MFH has made significant changes in its oversight and monitoring of borrower compliance with program regulations.

Information technology advances have assisted the MFH field staff in conducting more focused and comprehensive physical inspections at properties, including the ability to obtain immediate feedback from borrowers and management agents on corrective action timetables. The use of a hand-held device to record, capture, and deliver results of both physical and management oversight reviews have improved turn-around time for follow-up to ensure that corrections are made.

MFH also uses an automated budget analysis tool that flags high project expenses and high rent increases; such flags cause field staff to analyze more closely repair and maintenance activities, and proposal capital improvements to be paid for through higher rents. The availability of field staff to be within reach of the properties financed by the Direct Loan programs expands the agency's capability to ensure the improvements planned are properly executed.

MFH participates in the White House Physical Inspection Alignment Initiative, which encourages Federal housing assistance programs to work cooperatively in areas of overlap. Physical inspections are one such area, where properties financed by MFH may also have Low Income Housing Tax Credits or Section 8 rent assistance support. In these instances, the Alignment Initiative targets these joint properties to share physical inspection information among the affected agencies—which serves to reduce duplication while also focusing oversight on properties with higher Federal investment dollars.

#### RURAL HOUSING MATURING MORTGAGES

*Question.* Over the next several years most of the section 515 loans outstanding will mature. By 2020, close to 75 percent of section 515 loans, totaling over 400,000 units, will have reached the end of the loan term. Rental assistance is limited to tenants living in projects financed with section 514 and 515 loans. As property owners pay off the loans for the projects, the tenants lose eligibility for rental assistance. Most of these rural rental housing projects are in small communities and their only market is affordable housing.

What steps has USDA taken thus far to address this issue and is there a long term plan to ensure that this housing continues to be available for the low income and elderly households?

*Answer.* Rural Development is very concerned with the potential loss of affordable housing as our Section 515 direct loans mature, because that housing could be lost in the community and the rental assistance support would no longer be available to the families in that property. If that RD housing is lost, the very low income families living there may have no other affordable housing in which to live.

In response, RD has provided a number of options for owners to keep their RD loan and protect the families living there.

- The borrower can apply through RD's Preservation NOFA for a deferral of their maturing mortgage for up to 20 years;
- The borrower can receive priority points if they choose to apply for both the deferral and additional RD funding for rehabilitation of property;
- The borrower can request a re-amortization and modification of the maturing loan to extend the loan term up to 20 years;
- If owners go through the prepayment process to allow their tenants may be eligible to receive housing vouchers.

In addition to these steps, the Department has also offered Letters of Priority Entitlement to tenants in maturing mortgages. Holding this Letter will allow the tenant to be placed at the top of the waiting list for any RD property in order to continue living in affordable housing. The Agency may be authorized to transfer the unused rental assistance to a new RD property in limited circumstances. The Department has also included in the fiscal year 2016 President's Budget a legislative proposal to allow Rural Development housing vouchers to be used by tenants in these maturing mortgage properties.

Current voucher program appropriations language limits use to tenants in situations where the owner is prepaying the RD mortgage.

#### RURAL HOUSING 502 DIRECT LOANS

*Question.* In fiscal year 2014, approximately \$100 million in the 502 direct home ownership loan program was unspent. In fiscal year 2015 USDA obligated all the funds available.

Please explain the steps you have taken to improve processing of direct home-ownership loans.

*Answer.* In fiscal year 2015, delivery of the 502 direct home ownership loan program was a high priority for USDA. That priority continues in fiscal year 2016, and will be reinforced with automated underwriting, streamlining of the credit report

process, and additional program training. A certified packager program final rule will be implemented provided that prohibitory “pilot” language is removed from the final USDA fiscal year 2016 appropriations bill. This regulation will enhance our partnership with certified loan packagers and further enhance program delivery.

#### RURAL HOUSING SECTION 502 GUARANTEED

*Question.* The President’s Budget requests authority to allow RHS to allow direct endorsement for lenders rather than processing all guaranteed loans in-house.

Please provide additional information on how this authority would work.

*Answer.* The agency will reserve delegated underwriting authority for select lenders meeting established criteria. Lenders will not qualify for consideration unless they have strong loan performance characteristics as an approved program lender for a period of 2 years or more. Additional prerequisites will be established by the Secretary to further determine a lender’s eligibility for delegated authority. For example, the lender would need to demonstrate a proven history of delinquency rates below the national average for all approved lenders. Lenders granted this authority will be required to maintain certain credentials and training requirements to retain such status.

To implement delegated underwriting authority the Agency will need to enhance its lender monitoring and reporting capabilities in its Guaranteed Underwriting System. Once the agency secures funding, the necessary IT development will take approximately 2 years.

*Question.* In fiscal year 15 RHS obligated roughly 78 percent of Section 502 Guaranteed, yet managed to obligate 99 percent of 502 direct.

Please provide background on this discrepancy.

*Answer.* The observed discrepancy is more reflective of operational differences than performance disparity between the Direct and Guaranteed programs. The \$24 billion program level Congress has established for the Single Family Housing Guaranteed Loan Program (SFHG) provides the program the capacity needed to accommodate fluctuating market demand, which can be significantly affected by the macro-economic environment, as in 2007. Should program funding be exhausted, thousands of lenders and potentially tens of thousands of prospective borrowers could be negatively affected. This would have a tremendously detrimental effect on program credibility. The lending capacity of this negative-subsidy program ensures that USDA can meet the mortgage credit needs of low and moderate income borrowers during periods of unexpected market volatility. It thereby provides a very valuable safeguard, preserving the viability of the program for future generations of rural Americans.

The successful obligation of all Section 502 Direct funding, reflects the strong demand for the program’s affordable financing terms, which enable low and very-low income borrowers without access to alternative sources of mortgage credit an opportunity for homeownership. This program, whose funding totals approximately 3.8 percent of the guaranteed program, is vitally important to rural America.

#### RURAL HOUSING SECTION 538 ELIGIBILITY FOR HOUSING COOPERATIVES

*Question.* USDA Rural Development has a long history of supporting agricultural cooperatives and cooperative businesses. Yet, there has been some confusion on why Rural Development does not provide financing for housing cooperatives. For many consumers in rural communities, especially seniors, a housing cooperative can be an affordable option to owning a home.

It is the Committee’s understanding that housing cooperatives are eligible for the 515 multi housing program, but not the 538 program, which is the more ideal program for financing.

Can you explain why the 538 program is not accessible to the financing of cooperatives? Can you provide to this Committee a solution to this issue?

*Answer.* RD has determined that under Section 538 of the Housing Act of 1949 (42 USC 1490p-2), loan guarantees under the Guaranteed Rural Rental Housing Program are not permitted for cooperative housing. An amendment to that section of the Act by Congress could permit an extension of guarantees to cooperative housing.

#### RURAL IN CHARACTER

*Question.* We understand your agency is working on guidance regarding the definition of “rural in character”—can you tell us where you are in that process, and what it means for homebuyers in rural communities?

*Answer.* RHS is continuing to refine the agency’s guidance with respect to the definition of “rural in character” in order to clarify the rural in character requirement

in a manner that is sufficiently practical for application in diverse towns and counties throughout rural America. The agency has reviewed the matter extensively and is currently evaluating the data and potential eligibility criteria necessary to achieve this purpose.

In response to public concern Rural in Character determinations were suspended. The suspension is allowing USDA Rural Development (RD) to review the public engagement and decisionmaking processes for 'rural in character' determinations. We are communicating with stakeholders and policy-makers about how best to ensure USDA rural housing programs serve communities with limited access to credit and few housing options. The temporary suspension of new RIC-related designations will remain in effect until this evaluation process is completed.

#### RURAL UTILITY SERVICE—EXISTING WATER AND WASTE DISPOSAL LOAN PORTFOLIO

*Question.* There are reports that the Department is considering a possible portfolio sale, similar to the one that took place in 1987. Given that the Department has not requested this authority, before considering such an action, the Subcommittee would request the following information:

Does the Department plan to discount any portion of an existing Water or Waste Water loan to the private sector and charge the difference to the mandatory account?

*Answer.* USDA is considering a participation transaction that would offer private entities a participation interest and would not discount any portion of existing RUS loans. The Department is working with the Office of Management and Budget (OMB) and the Department of the Treasury (Treasury) on how to bring such a transaction to market that will have no impact on the program's borrowers and protects the taxpayers' investment in USDA's program.

*Question.* Will the current borrower be allowed the same treatment to have their remaining balance discounted at the same level of the private investor?

*Answer.* USDA would not discount any portion of its existing loans.

*Question.* Will this impact the subsidy rate on the discretionary Water and Waste Water Direct loan?

*Answer.* We do not anticipate any impact on the future subsidy rate.

*Question.* Will the current RUS borrowers have to sign off on any modification or participating loan sale or prepayment?

*Answer.* A participation transaction would not require sign-off from the program's current borrowers.

*Question.* Will utility borrowers have a right for first refusal?

*Answer.* The transaction would have no impact on the program's borrowers, who would retain all the rights and protections that they currently have under the terms of their loan agreements.

*Question.* Is this is considered a modification; the current appropriation bill language does not include "modification" authority for this portfolio?

*Answer.* While the transaction would constitute a Government action, USDA is working with OMB on determining the cost of the transaction under the Federal Credit Reform Act of 1990.

*Question.* If this is considered a modification where the government takes an action to change the loan terms or conditions, wouldn't this be paid for by the discretionary account and require approval from Congress and most likely additional budget authority?

*Answer.* While the transaction would constitute a Government action, USDA is working with OMB on determining the cost of the transaction under the Federal Credit Reform Act of 1990.

*Question.* Why is the Department considering such a change without input of organizations that represent current borrowers or through consultations with Congress?

*Answer.* USDA has reached out to the National Rural Water Association (NRWA) and looks forward to briefing Congressional staff at the appropriate time once a proposal is completed. Secretary Vilsack met with NRWA leadership in November 2015; NRWA supports these efforts to bring infrastructure funding to rural America and is committed to working with USDA as the transaction moves forward.

*Question.* The Department has the authority to currently leverage loans, for example, couple a direct loan with a guarantee or private loan. Are you pursuing this activity?

*Answer.* Through existing business practices, USDA is leveraging private sector investment in this portfolio through bridge loans and interim financing as well as with guaranteed loan authority.

The proposed transaction discussed in previous answers incentivizes a forward commitment from the private sector to invest in rural water and waste infrastructure in rural communities with populations of more than 10,000, which are beyond the statutory reach of USDA's current water program, but are served by other USDA rural loan and grant programs. The target communities would also include those that became ineligible for USDA's water loans when their population level exceeded the 10,000 limit in the 2010 census.

*Question.* What happens in a disaster situation like with a hurricane where a community might lose half of their customer base and couldn't pay their full note? The Federal portion has some tools including deferring payments that provided relief to this borrower. Can the payment portion to the private investors be altered or deferred at the time of a disaster?

*Answer.* USDA would retain all of its current tools in providing relief to borrowers under duress. The investor would be made aware of these tools and would be subject to the same repayment risks as the Government in the transaction. Any losses would be shared by the investor and the Government.

#### STRATEGIC ECONOMIC AND COMMUNITY DEVELOPMENT INTERIM RULE

*Question.* In May, the USDA—RD published the “Strategic Economic and Community Development” Interim Rule for public comment. The Interim Rule implements the “Strategic Economic and Community Development” provision (Section 6025) of the Agricultural Act of 2014. To implement Section 6025, RD will reserve 10 percent of the funds appropriated to select RD programs each fiscal year to fund projects that support the implementation of strategic economic and community development plans across multi-jurisdictional areas.

Please provide an update on the implementation process for Section 6025, with emphasis on how RD has implemented the Community Economic Development team and what the next steps are.

*Answer.* In fiscal year 15, CF, WEP, B&I, and RBDG did not have set aside funds for 6025 due to time constraints. Instead, RD developed a Regional Development Priority (RDP) policy that offered an opportunity for project proposals submitted under the aforementioned underlying programs which are supportive of multi-jurisdictional plan to receive additional points. These project proposals were reviewed first and foremost based on the underlying program's regulation and policies. If a project was deemed eligible for the underlying program, it was then reviewed for 6025 requirements if the applicant submitted the required documentation for requesting RDP points.

RD received 47 total applications requesting RDP points broken down as follows:

- By program
  - 28 from CF
  - 6 from WEP
  - 13 from RBDG
  - 0 from B&I
- By State
  - CF: 18 from AR, 1 from IA, 2 from MN, 1 from NH, 1 from NJ, 1 from NJ, 2 from SC, 2 from VT
  - WEP: 2 from MN, 2 from NH, 1 from SC, 1 from VT
  - RBDG: 2 from AR, 1 from AZ, 1 from HI, 1 from MA, 1 from MD, 1 from MO, 1 from NC, 2 from NH, 1 from VA, 2 from VT

RD is in the process of making final awards for fiscal year 15. Among those awards from the CF, WEP, and RBDG, 26 awards will be to projects that received RDP points as follows:

- By program
  - 16 from CF
  - 3 from WEP
  - 7 from RBDG
- By State
  - CF: 15 from AR, 1 from VT
  - WEP: 1 from MN, 1 from NH, 1 from SC
  - RBDG: 1 from AR, 1 from AZ, 1 from MA, 1 from MO, 1 from NH, 1 from VA, 1 from VT

During fiscal year 16, RD is working to implement Section 6025 as a set aside. RD's Community Economic Development (CED) Team will help build capacity to ensure areas of high needs have multi-jurisdictional plans in place. This would enable these areas to identify needs, economic development priorities, partners, and projects needing assistance which are potential pipelines for CF, WEP, B&I, and RBDG. Once these areas have the plans in place, they can access the 6025 set

asides from these programs in fiscal year 16. Furthermore, the CED Team is reaching out to communities that have developed multijurisdictional plans in place to raise awareness about 6025 set asides.

*Question.* The Interim Rule defines ‘Plan’ as, “a comprehensive economic development or community development strategy that outlines a region’s vision for shaping its economy.” Do HUD’s Sustainable Communities Plan, USDA’s Stronger Economies Together Plans, and other Regional Comprehensive Plans fit into that definition? More specifically, what is covered under the Interim Rule’s definition of “plan”?

*Answer.* RD intends the definition of “plan” be inclusive rather than exclusive, but at the same time require the plan to address certain minimum elements in order to be effective in improving the economies of the region addressed by the plan.

The Rule defines Plan as follows: For the purposes of this subpart, a plan is a comprehensive economic development or community development strategy that outlines a region’s vision for shaping its economy. This strategy would cover, as appropriate and necessary, a wide range of aspects such as natural resources, land use, transportation, and housing. Such plans bring together key community stakeholders to create a roadmap to diversify and strengthen their communities and to build a foundation to create the environment for regional economic prosperity.

To be an acceptable plan for the purposes of the subpart, the plan must be supported by the jurisdictions affected by the plan and must address each of the following elements:

- The economic conditions of the region;
- the economic and community strengths, weaknesses, opportunities, and threats for the region, to include consideration of such aspects as the environmental and social conditions;
- strategies and implementation plan that build upon the region’s strengths and opportunities and resolve the weaknesses and threats facing the region;
- performance measures to evaluate the successful implementation of the plan; and
- support of key community stakeholders.

RD notes that inclusion of each of the five elements does not speak to the quality of the plan or to whether the plan has been adopted.

Generally, HUD’s Sustainable Communities Plans, USDA’s Stronger Economies Together Plans, and other Regional Comprehensive Plans fit into that definition. Additionally, EDA’s Community Economic Development Strategy plans generally fit into the definition of a plan as well. RD is actively reaching out to agencies and organizations which administer these plans to communicate the Section 6025 opportunity to their stakeholders with plans in place.

*Question.* In the scoring section of the Interim Rule, RD proposed to award two points for projects that utilize contributions from other Federal agencies. Are points awarded when state and local agencies provide similar investments? If not, why are they not calculated as part of the score for applications under the interim rule?

*Answer.* Points are not awarded for state and local agencies because of the language in the authorizing statute only refers to Federal agencies in 6025(c)(1)(C).

*Question.* Please explain how the implementation of Section 6025 will make it easier for rural communities to access targeted resources to invest in long-term economic and community development efforts?

*Answer.* Recognizing that rural communities have limited resources and myriad unique challenges to creating sustainable communities, Section 6025 of the 2014 Farm Bill is an opportunity to prioritize projects that support the implementation of a regional economic development plan. Rural communities who engage in regional collaboration plan and build strategically already increase their efficiencies and outcomes. As such, these communities who have a regional plan will further be able to utilize Section 6025 to access set aside funding that rewards regionalism and leverage CF, WEP, RBDG, and B&I programs—programs which provide resources which are fundamental to creating strong and sustainable communities—for the benefit of multiple jurisdictions.

---

QUESTIONS SUBMITTED BY SENATOR JOHN HOEVEN

RURAL UTILITIES ADMINISTRATOR BRANDON MCBRIDE

*Question.* The newly-created Broadband Opportunity Council which has been tasked with producing specific recommendations and guidance to increase broadband deployment recently released its report with recommendations that address regulatory barriers and encourage investment and training.

To what extent are you following the Council's recommendations?

*Answer.* The main recommendation to RUS in the report asks RUS to evaluate the long-standing Telecommunications Program to see if it could be expanded to include companies that traditionally have not qualified for the program. Today, the program is primarily structured for an Independent Local Exchange Carrier, so RUS will explore whether others, including cable companies, Competitive Local Exchange Carriers, and wireless providers could qualify under the statutory requirements.

*Question.* I believe that investment in broadband connectivity is vital to the development of our rural communities, and that streamlining and eliminating duplicative programs is a step in the right direction towards increased access. That being said, what specific actions are you pursuing to break down regulatory barriers and increase rural broadband investment?

*Answer.* In addition to the items mentioned above, RUS is working with sister Rural Development Agencies to explore any synergies between programs and make applying for broadband funding to be a one-stop-shop for all RD programs. In addition, we are in discussions with the FCC to be better prepared for the changes that they are making to the telecom industry and will make modifications to our financing programs that are in line with these changes.

*Question.* As well, I think it is especially important that the regulatory processes initiated by the Council's recommendations are transparent, fair, and open. To this extent, what steps are you taking to improve your collaboration with the private sector and State, Local, and Tribal governments in the rulemaking process?

*Answer.* Prior to new regulations being published, RUS conducts Tribal consultations to get their input and make sure that their concerns are addressed in any new regulation.

In addition, RUS is holding regional workshops with the focus not only on the RUS financing program but also on how to use broadband services for rural economic development. Attendees to these events in Tribal representatives, local and state government, private companies and others.

*Question.* How do you plan on leveraging public private partnerships to maximize the Federal government's investment in rural broadband services?

*Answer.* RUS will work with private investors to leverage the amounts that are available for funding. Strong local support is required for a broadband service provider to succeed.

The Broadband Opportunity Council included a proposal from the Rural Utility Service that would provide the Secretary of the Department of Agriculture with greater flexibility to approve financing under the Rural Utility Service's Telecommunications Infrastructure Loan Program for entities in areas that are determined to be underserved or unserved.

*Question.* What steps will be taken with regard to this recommendation to prevent duplication or other forms of unnecessary overbuilding?

*Answer.* The Broadband Program statute and regulations already address overbuilding within the eligibility requirements, and the Infrastructure Program statute and regulations already require a finding of non-duplication of facilities before a loan can be made.

---

#### QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY

##### RURAL ENERGY SAVINGS PROGRAM (RESP)

*Question.* At the fiscal year 16 USDA budget hearing, Secretary Vilsack pledged to implement the Rural Energy Savings Program (RESP) that was authorized in the Farm Bill. We understand that Rural Development already offers an Energy Efficiency and Conservation Loan Program, which is similar to RESP in several respects. However, there are key advantages to the RESP program that we believe will cause it to be much more effective.

What progress has Rural Development made to fulfill the Secretary's commitment to establish this program?

*Answer.* The Energy Efficiency and Conservation Loan Program (EECLP) was inspired by efforts to enact the Rural Energy Savings Program (RESP). RUS has worked to identify how we might implement RESP. The key difference between EECLP and RESP is that EECLP offers very low interest rates to utilities while RESP provides for a zero interest rate. A zero interest rate would require budget authority to cover the costs of the program. EECLP loans do not require budget authority for the cost of the loan because of the electric program's negative subsidy rate. RD will continue to work with the Committee to further advance energy efficiency.

*Question.* When do you expect regulations to be published?

*Answer.* We do not have a set timeline, but we will continue to keep the Subcommittee informed as we move forward. We will continue to work with USDA staff and the Committee to determine how to best implement energy efficiency programs.

*Question.* Please let us know if there is anything this Subcommittee can do to help you expedite this process.

*Answer.* We will continue to keep the Subcommittee informed as we work to advance energy efficiency programs for rural areas.

#### PRIVATE INVESTMENT IN RURAL INFRASTRUCTURE

*Question.* Secretary Vilsack has long expressed an interest in promoting private sector investment in rural infrastructure. It is believed that private sector markets neglect rural investment opportunities due to unfamiliarity and the relatively smaller project sizes. He has viewed the Water and Waste Disposal direct loan portfolio as a vehicle to educate the private sector on the excellent prospects that can be available.

Please describe, in very specific terms, the current initiative that is under consideration.

*Answer.* The United States faces costly upgrades to aging and deteriorating drinking and wastewater infrastructure. Given the stress on public budgets, governments are unlikely to have the capacity to fill this funding gap. The gap is particularly problematic for rural communities that often depend on Federal and state grant and loan programs to finance their water infrastructure projects. While larger, urban areas can issue public bonds to pay for major improvements, rural communities have limited access to these financial markets, restricting their ability to independently finance projects.

USDA recognizes the need for additional investment in rural water infrastructure and is exploring how institutional investors (e.g. pension funds) could play a role in filling some of the gap. The challenge we face is that loan amounts needed to support rural water projects are often too small for institutional investors to consider making on a one-off basis, especially for those without prior experience in rural water lending.

To incentivize institutional investors to enter the lending market for rural water projects, USDA is considering offering an investor a participation interest in a small portion of the Department's water loan portfolio. In exchange, the investor would make a forward commitment to a certain amount of new loans in support of rural water projects. The policy goal of such a transaction is to create an initial investment of scale suitable for institutional investors to consider entering the market.

In fulfilling its forward commitment, the investor would target rural communities with populations of more than 10,000, but less than 20,000 which are beyond the statutory reach of USDA's current water program, but are served by other USDA rural loan and grant programs. The target communities would also include those that became ineligible for USDA's water loans when their population level exceeded the 10,000 limit in the 2010 decennial census.

*Question.* What are the administrative burdens, and how much will they cost, to implement this initiative?

*Answer.* There will be no material administrative burdens as a result of the transaction.

*Question.* Will Rural Development continue to be responsible for servicing the loans?

*Answer.* Yes.

*Question.* Will Rural Development be responsible for outreach and promotion of the initiative, and finding new projects that might be funded?

*Answer.* No.

*Question.* What are the current and future Credit Reform costs of this initiative? That is, what will be required in terms of current budget authority and what will be the future effects on the program subsidy rate?

*Answer.* While the transaction would constitute a Government action, USDA is working with OMB on determining the cost of the transaction under the Federal Credit Reform Act of 1990 (FCRA). USDA is planning to structure this transaction to have no cost under FCRA. We do not anticipate any impact on future subsidy rates for the water and waste disposal loan program.

*Question.* Will private sector participants receive a discount on the loans involved?

*Answer.* USDA would not discount any portion of its existing loans.

*Question.* Will current borrowers be offered the right of first refusal, if their loan is being sold or participated out? If not, why not?

*Answer.* No. At this time USDA does not anticipate offering borrowers the right of first refusal. The transaction would have no impact on the program's borrowers, who would retain all the rights and protections that they currently have under the terms of their loan agreements.

*Question.* Will current borrowers retain servicing options they currently are entitled to?

*Answer.* Yes.

*Question.* Will this initiative reduce the debt burden on borrowers?

*Answer.* No, borrowers will continue to be responsible for their current obligations.

*Question.* How many water and waste projects go to poverty areas or areas in dire need of these services?

*Answer.* In fiscal year 2015 RUS funded 340 water and waste projects, totaling \$676 million, in persistent poverty counties and rural areas where twenty percent or more of its residents are living in poverty. These investments are part of a continuing USDA focus on addressing the needs of market poverty communities in rural America.

#### RENTAL ASSISTANCE

*Question.* We understand that funding to renew Rental Assistance agreements in fiscal year 15 was exhausted in August. For those projects that did not get renewed, what protection did you provide to the tenants against unaffordable rent increases?

*Answer.* Approximately 44 properties out of RD's 14,600 Multi-Family Housing portfolio (about 0.3 percent) were affected by the prohibition against a second renewal of Rental Assistance in fiscal year 15. RD's field staff worked with the property owners to develop "relief plans" intended to keep as much money in the property's operating account as possible, so that no change in tenant contribution would be necessary. In our discussions with borrowers, we urged them to use all the relief tools available, to mitigate the need for an increase in tenants' contribution towards rent. Forty-one owners of MFH properties elected to utilize the tools we offered (defer RD mortgage payment; suspend deposits to reserve account; use the reserve account for operating expenses; allow over income tenants to fill vacant units; allow for a borrower loan to the property).

*Question.* Did any tenants suffer substantial rent increases?

*Answer.* RD did not approve any rent increases as a result of the inability to renew these RA agreements. A few owners did notify their tenants that their portion of the rent payment would increase. At this time, we do not have quantified figures as properties report on a monthly basis; however, we can get that information for you.

*Question.* What assistance are you providing to project owners until Rental Assistance agreements are renewed under the Continuing Resolution?

*Answer.* RA funds were received under the Continuing Resolution and an Exception Apportionment. These funds were immediately made available to renew Rental Assistance agreements. As of November 4, more than \$478 million has been used to renew RA agreements. For properties that ran out of funding in October or earlier, their RA agreements will provide funds effective October 1.

*Question.* When a Rental Assistance unit becomes vacant, regulations require that the unit be offered to the lowest income applicant on the waiting list. With this requirement, how do you accurately estimate future Rental Assistance needs?

*Answer.* We believe very strongly that our mission is to serve the needs of the most vulnerable residents in rural communities. In doing so we acknowledge the difficulty in accurately estimating future rental assistance needs, in an effort to address the issue Rural Development has taken the initiative to improve the accuracy of its estimation process by updating the methodology RD has been using to calculate the dollar amounts needed on an RA Agreement.

*Question.* What is the magnitude of the fiscal year 15 Rental Assistance shortfall?

*Answer.* As indicated during the hearing, RD did not have sufficient funding for the RA Agreements due for renewal in September of 2015. There were 905 properties that requested RA that had less than a full month's RA payment remaining in their agreement. Consequently, the RA shortfall in September was \$3,873,518. The shortfall was due to: more RA units than expected needing renewal; and an increase in per unit costs. The higher than expected number of renewals occurred in part due to the need to fund a second renewal for properties that were not subject to the re-renewal prohibition. The higher than expected per unit costs reflected inflationary increases not anticipated in 2013 when the fiscal year 2015 budget was prepared. Harvard's Joint Center for Housing Studies' analysis of the consumer price index (CPI) for contract rents (a broad and therefore conservative measure) indicates that rents are climbing at an accelerating rate. Nominal rents were up 3.5

percent during the 12 months ending September 2015, which is considerably higher than the 1.6 percent provided by budget guidance in 2013.

*Question.* What is the amount that is needed in fiscal year 16 to fund all expiring Rental Assistance contracts?

*Answer.* The current appropriation of \$1,389,695,000 is sufficient to fund all expiring Rental Assistance contracts in fiscal year 16.

*Question.* What internal changes are you making to your estimation process to ensure more accurate budget requests in the future?

*Answer.* The development of the "Rental Assistance Obligation Tool" in 2015 represents a huge step forward in the RA estimation process. The Obligation Tool will calculate properties' estimated needs based on each individual property's RA history rather than the former method of using a state-wide estimation process. The Tool includes an updated calculation methodology for forecasting that is based on:

- The average amount of RA the property used during the most recent 12 months;
- Higher weighting of the more recent months' RA use to reflect the most current tenant characteristics;
- Adjustments for any implemented and planned rent increases;
- An inflation factor to adjust for any time lag between the estimate and when funds will be needed.

The Tool became effective October 1. We are confident that this new methodology will significantly increase the accuracy of our estimation process.

*Question.* Can you assure this Subcommittee that the fiscal year 17 budget request will not understate the need to renew expiring Rental Assistance agreements?

*Answer.* We are confident that the new RA Obligation Tool will substantially reflect the most current needs of the property.

#### MATURING MORTGAGES

*Question.* The number of Rural Development-financed multi-family housing loans maturing each year is increasing and will reach 1,100 projects per year in 2019. When these loans are paid off, the projects will no longer be in USDA's affordable housing program, and will not have access to Rental Assistance or loan servicing options that Rural Development can offer.

What is Rural Development doing to keep these projects in the affordable housing program?

*Answer.* RD is very concerned with the potential loss of affordable housing as our Section 515 direct loans mature, because that housing may be lost in the community and the rental assistance support would no longer be available to the families in that property. If that RD housing is lost, the very low income families living there may have no other affordable housing in which to live.

In response, RD has provided a number of options for owners to keep their RD loan and protect the families living there.

- The borrower can apply through RD's Preservation NOFA for a deferral of their maturing mortgage for up to 20 years;
- The borrower can receive priority points if they choose to apply for both the deferral and additional RD funding for rehabilitation of property;
- The borrower can request a re-amortization and modification of the maturing loan to extend the loan term up to 20 years;
- If owners go through the prepayment process, their tenants may be eligible to receive housing vouchers.
- RD has also proposed legislation in the 2016 budget to extend housing voucher protection to tenants in properties with a mortgage that matures and the owner is not willing to extend the affordable housing feature of that property.

*Question.* Do current project owners generally want to remain in the program or graduate out?

*Answer.* We believe that most owners wish to remain in the program, because of the stability that the rental assistance benefit provides and the favorable financing available through our 515 and Preservation and Revitalization programs. Many of these owners also share our commitment to provide affordable housing to the low income residents that we both serve. We thank them for their continued commitment.

*Question.* Have you surveyed project owners to determine what number would like to remain in the program and where those projects are located?

*Answer.* RD has not performed a survey of all of the owners of approximately 11,500 properties with mortgages maturing through 2024. However, RD field staff do contact individual owners of properties with mortgages maturing in the next few years to learn those owners' plans for the property, and to explain the options the owners may have to keep the affordable housing in the program. RD has also had

numerous discussions with organizations active in this issue to get a general sense about the industry's interest in opportunities to retain this critically needed affordable housing.

*Question.* How are you working with owners and housing advocates to develop new options to retain properties in the affordable housing program?

*Answer.* RD recognizes the importance of our non-profit partners in retaining our affordable housing. We have looked for ways to encourage non-profits to take over this housing; one option that we have used is to promote the use of Section 515 loans to finance the acquisition of a maturing mortgage property from the existing owner. The new 515 loan extends the availability of that housing by another 30 years.

#### MULTI-FAMILY HOUSING PRESERVATION PILOT

*Question.* Over 14,000 affordable multi-family housing projects in rural America have been financed using USDA loans. These projects include over 475,000 housing units for low and very low income rural households. However, the average age of these projects exceeds 25 years.

With projects this old, what is Rural Development doing under the Rural Housing Preservation Pilot to improve their physical condition and to mitigate issues of deferred maintenance?

*Answer.* Since its authorization as a demonstration program in 2006, RD has been actively engaged in the preservation of its Section 515 portfolio through its Multi-Family Preservation and Revitalization (MPR) program. Through the end of fiscal year 2015, RD has obligated \$1.051 billion for the rehabilitation of 982 properties and more than 33,000 units of affordable housing. MPR has also facilitated a high level of cooperation with state housing finance authorities by leveraging billions of dollars in tax credits to stretch our limited appropriation dollars. As part of the application process for MPR funding, RD requires the property owner to address any immediate or near term property physical condition issues, including deferred maintenance. In addition, RD underwrites the loan application to ensure sufficient funds will be available to long-term physical issues as they arise.

In order to continue making progress in our revitalization efforts, RD has requested that Congress authorize the MPR program permanently. If the program was permanently authorized, the Agency could create regulations to institutionalize the program's benefits and signal to potential program participants that both the Executive and Legislative branches of the Federal government are committed to the revitalization of our affordable housing.

*Question.* How is Rural Development working with housing advocates, owners, and other interested parties to develop new options to preserve this valuable affordable housing stock.

*Answer.* RD recognizes the importance of our non-profit partners in retaining our affordable housing. We have looked for ways to encourage non-profits to take over this housing; one option that we have used is to promote the use of Section 515 loans to finance the acquisition of a maturing mortgage property from the existing owner. The new 515 loan extends the availability of that housing by another 30 years.

*Question.* One concern we frequently hear is that Rural Development is unable to expedite the transfer of a property from the current owner to a non-profit purchaser. These transactions typically take 18 months or more, which places incredible burdens on the buyers in terms of holding together financial packages. What are you doing to streamline and accelerate this process?

*Answer.* Stakeholders have expressed concerns about property transfer processing times. Based on those concerns, RD undertook a business process improvement to streamline the transfer process, reduce processing times, and increase consistency and transparency in the transfer process. In the spring of 2015, RD rolled out a transfer assessment tool. This tool was provided to stakeholders, including property owners, and training was provided to ease the use of the tool. The tool created consistency in underwriting transfer applications and increased transparency by ensuring all parties in the transfer have access to the same review tool. In addition, RD adopted several industry standards into its transfer policies, to ensure more consistent approval standards that are used by all funders in the transfer financial package.

*Question.* What is the average time required now to execute a property transfer?

*Answer.* Based on preliminary data, the average time to process, approve, and close a transfer from the date of receipt of a complete application package in fiscal year 2015 was 126 days. This is a reduction of 31 days, or nearly 20 percent, from

prior years. As we continue to make improvements to the process, we expect transfer processing to continue to improve.

#### SINGLE FAMILY HOUSING DIRECT LOAN PROGRAM

*Question.* The single family housing direct loan program is Rural Development's flagship program providing homeownership opportunities to low and very low income rural households. For years this program has offered the chance for successful homeownership to thousands of rural households who otherwise would be denied this opportunity. This has always been one of the most popular programs of this Subcommittee and ample funding is provided each year.

Were you able to obligate all of the funds available in fiscal year 15?

*Answer.* Yes, fiscal year 2015 funds were fully utilized on September 21, 2015.

*Question.* What changes are you putting in place for fiscal year 2016 to ensure that the funding provided will be entirely utilized, and not require the extraordinary efforts that were necessary in fiscal year 2015?

*Answer.* In fiscal year 2015, delivery of the 502 direct home ownership loan program was a high priority for USDA. That priority continues in fiscal year 2016, and will be reinforced with automated underwriting, streamlining of the credit report process, and additional program training. A certified packager program final rule will be implemented provided that prohibitory "pilot" language is removed from the final USDA fiscal year 2016 appropriations bill. This regulation will enhance our partnership with certified loan packagers and further enhance program delivery.

#### NEW POVERTY PILOT PROGRAM

*Question.* Recently the Administration announced a new multi-agency anti-poverty initiative, the "Rural IMPACT" demonstration project. Ten rural communities were selected to receive special technical assistance for 6 months, to develop plans to address the problems of poverty in their communities.

Please describe the Rural IMPACT initiative and what is expected to be accomplished.

*Answer.* Recognizing that every child, no matter where she is born, should have an opportunity to succeed, the White House Rural Council launched "Rural Impact", a cross-agency effort to combat poverty and improve upward mobility in rural and tribal places. And in August, HHS announced a new demonstration project, Rural Integration Models for Parents and Children to Thrive (IMPACT), to help communities adopt a two-generation approach to addressing the needs of both vulnerable children and their parents, with the goal of increasing parents' employment and education and improving the health and well-being of their children and families. Often, programs are structured to serve either adults or children, rather than focusing on the entire family to improve outcomes. The Rural IMPACT Demonstration helps communities adopt a comprehensive, whole-family framework for addressing child poverty, such as through facilitating physical colocation of services, universal "no wrong door" intake, referral networks, shared measurement systems, and use of technology to deliver services.

*Question.* How were the ten rural communities selected?

*Answer.* A process was led by HHS that included communities submitting letters of interest in participation in the demonstration. The Demonstration is administered by HHS with support from the Community Action Partnership and the American Academy of Pediatrics, and implemented in collaboration with the U.S. Departments of Agriculture, Education, and Labor, Appalachian Regional Commission, Delta Regional Authority, and the Corporation for National and Community Service (CNCS).

*Question.* Why do you think 6 months to develop local plans and then 6 months to implement those plans is adequate to produce visible results?

*Answer.* We believe that with intensive technical assistance, including individualized expert coaching, site visits, and peer learning, as well as increased capacity in the form of AmeriCorps VISTA volunteers, rural communities can make important program and system adjustments to intentionally align intensive, high-quality, adult-focused services with intensive, high-quality, child-focused programs.

*Question.* How will success be measured?

*Answer.* Over the long term, key outcomes would include: increased enrollment in quality early childhood programs; increased high school/GED and post-secondary credentials for parents; increased parental employment; and increased child and family well-being. Recognizing that we are limited in the outcomes we can expect within just 1 year, a process evaluation will empirically describe the Rural IMPACT intervention, its processes, the site-level activities that resulted, and the experiences of key individuals and teams involved.

*Question.* What will this demonstration project cost and from where are the funds coming?

*Answer.* USDA Rural Development has contributed \$250,000 for AmeriCorps VISTA volunteers to better coordinate rural development programs of Federal, state and local governments in the designated rural areas. The remaining resources are contributions from other participating agencies.

#### LOAN PORTFOLIO CREDIT QUALITY

*Question.* Rural Development has the difficult task of providing loans to rural individuals, organizations, and communities that have limited means and often cannot obtain commercial credit. The outstanding loan portfolio now exceeds \$210 billion.

Please discuss the credit quality of the portfolio, and whether or not delinquencies and loan losses are remaining steady or declining.

*Answer.* In looking at Rural Development's portfolio in its entirety, one measure that is tracked is the percentage of delinquent principal greater than 1 year. For fiscal year-end 2012, 2013, 2014, and 2015, those figures were 2.19 percent, 1.91 percent, 1.96 percent and 2.00 percent respectively. Therefore the portfolio as a whole has been fairly consistent at the 2 percent range.

Rural Development does, however, have a vast array of programs as represented in the portfolio reports that follow. Four years have been provided for comparison purposes of each program.

Loan loss data has also remained consistent during the last 4 years. For 2012, 2013, 2014, and through June of 2015, percentages have been .51 percent, .61 percent, .53 percent, and .46 percent respectively.

The information is submitted for the record.

[The information follows:]

## RURAL DEVELOPMENT LOAN PORTFOLIO AS OF SEPTEMBER 30, 2012

Loan Portfolio	# of Loans	Amount of Principal Outstanding	Delinquent Loans > 30 days				Delinquent Loans > 1 Year			
			# Loan Delinq.	% Loan Delinq.	Delinquent Principal balance	% Delq. Prin.	# Loan Delinq.	% Loan Delinq.	Delinquent Principal balance	% Delq. Prin.
Direct Portfolio										
Housing and Community Facilities										
Single Family Housing .....	307,883	\$15,776,794,078	70,151	22.78	\$3,860,545,020	24.47	20,612	6.69	\$1,075,339,610	6.82
Multi-Family Housing .....	25,488	\$11,161,277,000	*321	**2.11	\$206,782,018	1.85	*184	**1.21	\$126,938,039	1.14
Community Facility .....	6,164	\$4,165,281,000	144	2.34	\$180,241,446	4.33	66	1.07	\$85,471,316	2.05
Total Housing & Community Fac. ...	339,535	\$31,103,352,078	***70,295	***22.38	\$4,247,568,484	13.66	***20,678	***6.58	\$1,287,748,965	4.14
Utilities										
Water & Waste .....	17,836	\$12,004,297,000	93	0.52	\$125,725,161	1.05	57	0.32	\$80,159,255	0.67
Electric .....	3,203	\$43,087,376,196	1	0.03	\$1,447,861	0.00	1	0.03	\$1,447,861	0.00
Telecommunications .....	1,975	\$4,656,650,125	31	1.57	\$267,219,531	5.74	26	1.32	\$233,892,463	5.02
Total Utilities .....	23,014	\$59,748,323,321	125	0.54	\$394,392,553	0.66	84	0.36	\$315,499,579	0.53
Business and Cooperative										
Business and Industry .....	55	29,854,000	23	41.82	\$22,212,832	74.40	17	30.91	\$20,987,391	70.30
RMAP .....	142	14,914,045	10	0.00	\$0	0.00	0	0.00	\$0	0.00
Intermediary Relending Prog/HHS .....	1,028	\$453,693,800	12	1.17	\$5,253,101	1.16	5	0.49	\$3,575,574	0.79
Rural Economic Development .....	352	\$112,564,484	2	0.57	\$400,371	0.36	0	0.00	\$0	0.00
Total Business & Cooperative .....	1,577	\$611,026,329	37	2.35	\$27,866,304	4.56	22	1.40	\$24,562,965	4.02
Total Direct Portfolio .....	364,126	\$91,462,701,728	***70,457	***20.81	4,669,827,341	5.11	***20,784	***6.14	1,627,811,509	1.78
Guaranteed Portfolio										
Housing and Community Facilities										
Single Family Housing .....	671,274	\$75,683,366,487	88,532	13.19	\$9,628,542,279	12.72	16,930	2.52	\$1,883,300,769	2.49
Multi-Family Housing .....	550	\$668,204,431	3	0.55	\$6,006,470	0.90	2	0.36	\$4,278,232	0.64
Community Facility .....	713	\$1,173,174,000	21	2.95	\$49,050,168	4.18	9	1.26	\$22,274,686	1.90
Total Housing & Community Fac. ...	672,537	\$77,524,744,918	88,556	13.17	\$9,683,598,917	12.49	16,941	2.52	\$1,909,853,687	2.46
Utilities										
Water & Waste .....	69	\$90,699,867	0	0.00	\$0	0.00	0	0.00	\$0	0.00
Electric/Other .....	17	\$289,496,096	0	0.00	\$0	0.00	0	0.00	\$0	0.00
Total Utilities .....	86	\$380,195,963	0	0.00	\$0	0.00	0	0.00	\$0	0.00
Business and Cooperative										
Business and Industry .....	3,752	\$7,089,217,252	263	7.01	\$549,965,422	7.76	175	4.66	\$329,952,765	4.65
Total Business & Cooperative .....	3,752	\$7,089,217,252	263	7.01	\$549,965,422	7.76	175	4.66	\$329,952,765	4.65
Total Guaranteed Portfolio .....	676,375	\$84,994,158,133	88,819	13.13	10,233,564,339	12.04	17,116	2.53	2,239,806,452	2.64
Total Loan Portfolio .....	1,040,501	\$176,456,859,861	***159,276	***15.69	\$14,903,391,680	8.45	***37,900	***3.73	\$3,867,617,961	2.19

## RURAL DEVELOPMENT LOAN PORTFOLIO AS OF SEPTEMBER 30, 2013

Loan Portfolio	# of Loans	Amount of Principal Outstanding	Delinquent Loans > 30 days				Delinquent Loans > 1 Year			
			# Loan Delinq.	% Loan Delinq.	Delinquent Principal balance	% Delq. Prin.	# Loan Delinq.	% Loan Delinq.	Delinquent Principal balance	% Delq. Prin.
<b>Direct Portfolio</b>										
Housing and Community Facilities	299,935	\$15,593,598,443	72,565	24.19	\$4,044,744,331	25.94	24,517	8.17	\$1,276,738,913	8.19
Single Family Housing	24,973	\$11,060,153,000	**279	**1.87	\$182,852,919	1.65	*194	**1.30	\$139,950,212	1.27
Multi-Family Housing	6,121	\$4,708,785,000	130	2.12	\$141,414,500	3.00	75	1.23	\$83,623,935	1.78
Community Facility	331,029	\$31,362,536,443	***72,695	***23.75	\$4,369,011,750	13.93	***24,592	***8.04	\$1,500,313,060	4.78
<b>Total Housing &amp; Community Fac. ...</b>										
Utilities	17,005	\$12,080,703,000	66	0.39	\$86,502,160	0.72	15	0.09	\$27,727,916	0.23
Water & Waste	3,086	\$45,790,844,797	12	0.06	\$19,663,035	0.04	1	0.03	\$1,403,971	0.00
Electric	1,822	\$4,576,769,673	30	1.65	\$292,421,343	6.39	21	1.15	\$146,904,096	3.21
Telecommunications	21,913	\$62,448,317,470	98	0.45	\$398,586,538	0.64	37	0.17	\$176,035,983	0.28
<b>Total Utilities</b>										
Business and Cooperative	46	\$24,954,000	18	39.13	\$18,933,059	75.87	12	26.09	\$18,017,166	72.20
Business and Industry	85	\$20,331,259	3	3.53	\$119,478	0.59	0	0.00	\$0	0.00
RWAP	1,048	\$440,390,800	15	1.43	\$6,535,033	1.48	5	0.48	\$2,716,201	0.62
Intermediary Relending Prog/HHS	361	\$123,615,495	1	0.28	\$175,000	0.14	0	0.00	\$0	0.00
Rural Economic Development	1,540	\$609,291,554	37	2.40	\$25,762,570	4.23	17	1.10	\$20,733,367	3.40
<b>Total Business &amp; Cooperative</b>										
Total Direct Portfolio	354,482	\$94,420,145,467	***72,830	***22.10	\$4,793,360,858	5.08	***24,646	***7.48	\$1,697,082,410	1.80
<b>Guaranteed Portfolio</b>										
Housing and Community Facilities	775,355	\$89,742,912,407	91,808	11.84	\$10,210,728,503	11.38	14,048	1.81	\$1,674,113,500	1.87
Single Family Housing	615	\$750,593,362	1	0.16	\$294,890	0.04	0	0.00	\$0	0.00
Multi-Family Housing	701	\$1,242,806,021	17	2.43	\$27,568,610	2.22	12	1.71	\$24,730,405	1.99
Community Facility	776,671	\$91,736,311,790	91,826	11.82	\$10,238,592,003	11.16	14,060	1.81	\$1,698,843,905	1.85
<b>Total Housing &amp; Community Fac. ...</b>										
Utilities	68	\$78,665,770	0	0.00	\$0	0.00	0	0.00	\$0	0.00
Water & Waste	17	\$273,519,135	0	0.00	\$0	0.00	0	0.00	\$0	0.00
Electric/Other	85	\$352,184,905	0	0.00	\$0	0.00	0	0.00	\$0	0.00
<b>Total Utilities</b>										
Business and Cooperative	3,516	\$6,706,971,282	219	6.23	\$476,680,469	7.11	143	4.07	\$299,493,509	4.47
Business and Industry	3,516	\$6,706,971,282	219	6.23	\$476,680,469	7.11	143	4.07	\$299,493,509	4.47
<b>Total Business &amp; Cooperative</b>										
Total Guaranteed Portfolio	780,272	\$98,795,467,977	92,045	11.80	\$10,715,272,472	10.85	14,203	1.82	\$1,998,337,414	2.02
<b>Total Loan Portfolio</b>	1,134,754	\$193,215,613,444	***164,875	***14.86	\$15,508,633,330	8.03	***38,649	***3.50	\$3,695,419,824	1.91

## RURAL DEVELOPMENT LOAN PORTFOLIO AS OF SEPTEMBER 30, 2014

Loan Portfolio	# of Loans	Amount of Principal Outstanding	Delinquent Loans > 30 days				Delinquent Loans > 1 Year			
			# Loan Delinq.	% Loan Delinq.	Delinquent Principal balance	% Delq. Prin.	# Loan Delinq.	% Loan Delinq.	Delinquent Principal balance	% Delq. Prin.
Direct Portfolio										
Housing and Community Facilities										
Single Family Housing .....	291,968	\$15,415,802,962	75,432	25.84	\$4,239,911,528	27.50	28,851	9.88	\$1,507,234,605	9.78
Multi-Family Housing .....	24,716	\$10,914,281,000	*287	**1.94	\$197,524,047	1.81	*65	**1.12	\$123,347,225	1.13
Community Facility .....	5,970	\$5,049,715,000	118	1.98	\$145,378,338	2.88	67	1.12	\$75,895,343	1.50
Total Housing & Community Fac. ...	322,654	\$31,379,798,962	***75,550	***25.36	\$4,582,813,913	14.60	***28,918	***9.71	\$1,706,477,173	5.44
Utilities										
Water & Waste .....	16,676	\$12,425,766,000	64	0.38	\$82,595,959	0.66	20	0.12	\$30,337,162	0.24
Electric .....	2,978	\$46,431,536,087	3	0.10	\$21,547,566	0.05	3	0.10	\$21,547,566	0.05
Telecommunications .....	1,525	\$4,411,669,475	51	3.34	\$369,748,850	8.38	30	1.97	\$243,883,830	5.53
Total Utilities .....	21,179	\$63,268,971,562	118	0.56	\$473,892,375	0.75	53	0.25	\$295,768,558	0.47
Business and Cooperative										
Business and Industry .....	40	\$23,569,000	17	42.50	\$18,952,098	80.41	14	35.00	\$18,064,832	76.65
RWAP .....	84	\$23,914,016	4	4.76	\$131,710	0.55	0	0.00	\$0	0.00
Intermediary Relending Program .....	1,061	\$422,227,000	11	1.04	\$3,959,006	0.94	4	0.38	\$2,160,790	0.51
Rural Economic Development .....	379	\$158,214,456	6	1.58	\$2,745,655	1.74	0	0.00	\$0	0.00
Total Business & Cooperative .....	1,564	\$627,924,472	38	2.43	\$25,788,469	4.11	18	1.15	\$20,225,622	3.22
Total Direct Portfolio .....	345,397	\$95,276,694,996	***75,706	***23.61	\$5,082,494,757	5.33	***28,989	***9.04	\$2,022,471,353	2.12
Guaranteed Portfolio										
Housing and Community Facilities										
Single Family Housing .....	873,186	\$102,281,768,559	97,688	11.19	\$10,985,775,598	10.74	14,573	1.67	\$1,736,154,464	1.70
Multi-Family .....	648	\$785,939,681	1	0.15	\$294,890	0.04	1	0.15	\$294,890	0.04
Housing Community Facility .....	684	\$1,247,462,398	15	2.19	\$51,969,241	4.17	8	1.17	\$18,610,338	1.49
Total Housing & Community Fac. ...	874,518	\$104,315,170,638	97,704	11.17	\$11,038,039,729	10.58	14,582	1.67	\$1,755,059,692	1.68
Utilities										
Water & Waste .....	74	\$96,223,011	0	0.00	\$0	0.00	0	0.00	\$0	0.00
Electric/Other .....	17	\$247,912,430	0	0.00	\$0	0.00	0	0.00	\$0	0.00
Total Utilities .....	91	\$344,135,441	0	0.00	\$0	0.00	0	0.00	\$0	0.00
Business and Cooperative										
Business and Industry .....	3,331	\$6,298,413,586	194	5.82	\$416,411,396	6.61	117	3.51	\$264,421,512	4.20
Total Business & Cooperative .....	3,331	\$6,298,413,586	194	5.82	\$416,411,396	6.61	117	3.51	\$264,421,512	4.20
Total Guaranteed Portfolio .....	877,940	\$110,957,719,665	97,898	11.15	\$11,454,451,125	10.32	14,699	1.67	\$2,019,481,204	1.82

# RURAL DEVELOPMENT LOAN PORTFOLIO AS OF SEPTEMBER 30, 2014—Continued

Loan Portfolio .....	# of Loans	Amount of Principal Outstanding	Delinquent Loans > 30 days			Delinquent Loans > 1 Year		
			# Loan Delinq.	% Loan Delinq.	Delinquent Principal balance	# Loan Delinq.	% Loan Delinq.	Delinquent Principal balance
Total Loan Portfolio .....	1,223,337	\$206,234,414,661	***173,604	***14.48	\$16,536,945,882	***43,688	***3.64	\$4,041,952,557
								1.96

\* Number of projects delinquent

\*\* The percent of projects delinquent: Number of projects delinquent divided by number of projects outstanding. There are 14,771 projects outstanding as of September 30, 2014.

\*\*\* Exclude Multi-Family Housing Projects (Direct)

## BROADBAND

*Question.* Rural Development has had the responsibility for some years of expanding access to high speed broadband services across rural America.

How successful has Rural Development been in expanding rural access to high speed broadband?

*Answer.* RUS has been very successful in expanding broadband service in rural areas.

Over 1.9 million Rural Subscribers since 2009. Based on projections from the project applicants in all RUS programs, 1.9 million rural households, businesses, farms, factories, schools, libraries, and healthcare facilities are anticipated to receive new or improved broadband services as a result of RUS funding.

Over \$6.7 Billion since 2009. RUS has provided over \$6.7 billion in loans and grants for wireline, wireless, and satellite broadband deployment through the Infrastructure Loan program, the ARRA Broadband Initiatives Program, and the Farm Bill Broadband Program.

Unserved Rural Communities Receive Broadband through RUS's Community Connect Program. Since 2009, RUS has awarded over \$77 million in grants to 74 unserved communities to provide broadband service at residences, businesses, and community centers.

*Question.* The fiscal year 14 Farm Bill required changes to the USDA loan program. Please describe the significant program changes.

*Answer.* The Farm Bill required the following changes to be incorporated into 7 CFR part 1738 which governs the Broadband Loan Program.

- Evaluation Periods—establishes at least 2 evaluation periods each year.
- Priority—requires the Agency to prioritize applications that offer service to the greatest proportion of unserved households.
- Minimum acceptable level of broadband service—establishes a minimum level for which Broadband Service is defined (4 Mbps down and 1 Mbps up) and requires the Secretary to review that definition at least once every 2 years.
- Eligible Service Area—changes the current 25 percent underserved requirement and replaces it with a 15 percent unserved requirement. Availability of service in an applicant's service territory is to be validated by the National Broadband Map and any other sources the Secretary may obtain. Determining Priority of Applications—existing service in an applicant's service territory is to be validated by one of three resources: (1) information certified by the affected community, city or county, or (2) demonstrated by the state broadband map or (3) as shown on the National Broadband Map.
- Public Notice Regarding Applications—requires the Agency to establish a fully searchable database that includes a notice regarding each application for funding which includes the applicant identity, description of proposed service area, the amount and type of support requested, the status of the application, the estimated number of households without broadband service, and a listing of the census blocks that will be served or service area map.
- Public Notice Regarding Awardees—requires the Agency to establish a fully searchable database that includes a notice of each entity receiving funding, including the name of the entity, the type of assistance received, the purpose of the funding, and a copy of the awardees semiannual report (redacting any proprietary info).
- Semiannual Awardee Reporting—borrowers are to submit a semiannual report for 3 years after the completion of the project which describes the use of the assistance, the estimated number of end users using or forecasted to use the new or upgraded system, and the borrowers progress towards fulfilling the objectives for which the assistance was provided (the number and location of residents and businesses receiving new and improved service, the speed of the broadband service, the average price of service along with any changes to the adoption rates).
- Term—if the project is serving an unserved area, the Agency may establish a limited initial deferral period or other term necessary to achieve financial feasibility and long-term sustainability of the project.

*Question.* Have any loans been made under the new program?

*Answer.* At the end of July 2015, RUS published the new regulation and opened up the first application window that is now required. The application window closed on September 30, 2015 and 15 applications were submitted for approximately \$118 million. RUS is currently reviewing the applications.

*Question.* What does the demand look like for the new program?

*Answer.* Based on the number of applications received for only a 2-month application window, demand for the program appears to be strong. RUS is also hearing

from many potential applicants that they are working on submitting applications during the next application window.

*Question.* Do you consider the BIP program a success? Why?

*Answer.* We consider the BIP program very successful. BIP funded 254 projects that are now providing broadband service to some of the hardest to reach rural areas. Over \$2.9 billion was expended to bring broadband service to rural America.

*Question.* Rural Development has funded a lot of “smart grid” projects. What is smart grid technology?

*Answer.* Smart grid technology facilitates communications and remote control of electric utility systems and business and residential consumers. Smart grid technology allows utilities to better manage loads and locate outages. Smart grid technology offers consumers the ability to remotely control heating and air conditioning systems. For instance, a consumer could have their AC unit connected to a smart grid service provider and could remotely lower the temperature in the house before they get home.

#### RURAL ENERGY FOR AMERICA PROGRAM (REAP)

*Question.* The REAP program can and is used by individual farmers and ranchers, and certain agricultural cooperatives, to increase the efficiency of their operations or generate renewable energy on farm. Irrigation districts apparently are not eligible to apply. However, at least in Oregon, when irrigation districts pipe canals they are often interested in doing renewable in-pipe hydropower generation and other types of energy efficiency improvements for their members.

Does USDA have the ability to adjust the REAP program to allow irrigation districts to apply, and is this something you have considered doing? This could be an additional way to assist drought affected communities, which is something we should all be working on.

*Answer.* Most irrigation districts are quasi-public districts that were formed under State statute and would not qualify for funding under REAP. A regulatory change would be required to make these entities eligible recipients under REAP. There are a handful of districts, however, that have formed irrigation cooperatives as an operating entity. These cooperatives could be considered eligible for REAP.

To be eligible for REAP, the applicant must be a small business or an agriculture producer, and non-profits and other public entities are not eligible to participate in REAP.

*Question.* The fiscal year 14 Farm Bill provided the REAP Program with \$50 million in mandatory funding yearly. Please provide an update on how REAP is doing.

*Answer.* Fiscal year 2015 Program level included \$83 million of grant funding and \$208 million of guaranteed loan funding, which came from two fiscal years of 2014 Farm Bill Funding and fiscal year 2014 Appropriations. The program utilized all of the grant funding and 75 percent of the guaranteed loan funds. The guaranteed loan funds was twice the amount of the previous historical record which was quite a feat as almost half the year was gone before guaranteed loans could be obligated. Unused guaranteed loan funds will be carried over into fiscal year 2016 and made available for lenders to access project financing shortly after October 1st, which will continue to make the program more accessible to applicants needing the funding.

On December 29, 2014 RD published a final rule that took into account the 2014 Farm Bill provisions as well as comments received on the REAP interim rule published in 2011 and the proposed rule published in 2013.

RD has developed a new suite of outreach materials and is currently engaged in an extensive outreach effort to potential applicants and lenders.

#### RURAL BUSINESS-COOPERATIVE SERVICE

*Question.* What is the status of the Biorefinery Assistance Program (Sec. 9003)?

*Answer.* RD published an Interim Final Rule on June 24, 2015 implementing the 2014 Farm Bill provisions. The new rule makes the program more accessible to facilities producing renewable chemicals and to facilities manufacturing renewable chemicals and other biobased outputs of biorefineries into end-user products. It also requires the Agency to ensure diversity in the types of projects approved. A cap on the amount of funding is provided for promoting biobased product manufacturing (no more than 15 percent of fiscal year 2014 and fiscal year 2015 mandatory funds). In addition to addressing the Farm Bill provisions, the Interim Final Rule makes other programmatic changes including an improved application process, enabling the flexibility to assess an application on a commercial lending framework or a project finance-based framework, simplifying the application scoring process, and improving a number of loan guarantee terms and conditions.

RD published a Notice of Solicitation for Applications on July 6, 2015 announcing the first application cycle with a deadline of October 1, 2015. The NOSA requires all persons who intend to file an application by October 1, 2015 to submit a Letter of Intent no later than September 1, 2015. Application cycles are every 6 months with applications deadlines of October 1 and April 1, which are preceded by Letters of Intent by September 1 and March 1.

RD received letters from 23 potential applicants expressing their intent to file an application for the application cycle ending October 1, 2015, requesting loan totaling \$900 million and project costs totaling \$1 billion. Of these 23, six submitted applications by the October 1 deadline while 11 potential applicants notified RD that they will submit their application for the April 1, 2016 application cycle because their lender was unable to complete the application by the October 1, 2015 deadline.

10/01/2015 Application Cycle:

—Six applications—six Biorefineries and no Biobased Product Manufacturing facilities.

—Loans requested range from \$9 million to \$250 million and total \$588 million

—Projects costs range from \$12 million to \$340 million and total \$895 million

—Three biorefineries will primarily produce advanced biofuels and three will primarily produce biobased products including renewable chemicals.

Between fiscal years 2009 and 2014, 42 applications were received. Of these 142 applications, 30 applications were either withdrawn by the applicant/borrower, determined by RD to be ineligible, or have had funds deobligated. Of the remaining 12 applications, RD has issued 11 conditional commitments,—of which two loans have gone into default and one loan was repaid in full—and one application is pending for which RD is preparing to enter into a conditional commitment in fiscal year 2016.

*Question.* How do RBS programs leverage private-public partnerships and outside funding?

*Answer.* While the Federal budget has increasingly been strained by competing funding priorities, demand for RBS programs continues to grow. Leveraging of program funds with outside (non-Federal funds) is an important tool that RBS uses to stretch Federal funds in improving conditions in the rural American communities that RBS serves.

RBS' success in this leveraging is enhanced by promoting partnerships between the public and private sectors. RBS efforts to leverage program funding includes Rural Development State and National Office outreach efforts to discuss the equity or matching requirements of RBS programs to stakeholders, and participation in regional and local listening sessions, one on one meetings with stakeholders and eligible entities, and interagency meetings or forums with other Federal and state agencies, community development organizations, and private foundations or investors.

In addition, at the individual project level, leveraging additional funding sources demonstrates that others believe in the project, and it contributes to the sustainability of a project, because those who sign on as partners at the beginning have an incentive to continue supporting the project after the RBS loan or grant is fully dispersed.

The following table summarizes RBS' success in leveraging from fiscal year 2009 through fiscal year 2015.

Programs	Fiscal year 2009–2014		2015	
	Total Funding	Leverage	Obligations	Leverage
B&I Guaranteed Loans .....	\$8,712.99	\$5,743.90	\$1,044.52	\$460.00
REAP .....	568.36	1,498.23	244.26	680.38
Biorefinery Assistance Program (9003) .....	1,037.68	1,198.96	80.00	70.48
RBOG .....	23.69	18.31		(see RBDG)
VAPG .....	108.49	47.88	44.48	50.24
RCDG .....	42.09	15.28	6.05	2.32
IRP .....	140.80	873.81	18.89	9.42
REDLoans .....	268.62	1,560.34	38.65	196.89
REDGrants .....	54.24	431.54	9.21	57.63
RBDG .....	223.65	283.32	27.84	29.61
RMAP .....	74.86	49.66	5.02	1143.71
Total RBS .....	11,255.46	11,721.25	1,518.92	1,600.68

NOTE: All figures are in \$ millions.

*Question.* What is the status of the REDLG program? Why have you not awarded funds since March?

*Answer.* We obligated all of the available RED loan funds by the end of March 2015. The program is oversubscribed, and experienced a dramatic funding cut from 2014 to 2015. In 2014, \$85.6 million in loans and \$9.2 million in grants were available and awarded. In 2015, less than half, or \$38.6 million in loans and \$9.2 million in grants were available.

*Question.* How do RBS programs support local food initiatives?

*Answer.* Local and regional food is the strongest food trend in decades and USDA and Rural Development are looking to build on this trend and facilitate consumer interest in reconnecting with all American agriculture and bridge the rural-urban divide. While limited by geographic borders, RD has sought to identify projects that while located in rural areas, can be used to support needs in urban and suburban areas. For example, working to link a rural produce marketing cooperative with an urban food retailer or market where there is a lack of affordable fresh produce. RD has also been active in the Know Your Farmer, Know Your Food initiative which emphasizes the need for a fundamental and critical reconnection between producers and consumers. RD continues to work to align existing programs with the needs of local and regional food systems; conducting outreach activities so that the linkages are understood; helping communities build local food systems by providing new initiatives; and engaging the American public in conversation about local and regional agriculture. RD has been engaged with other Mission Areas within USDA as well as other Federal agencies to collaborate and leverage resources and overcome these geographic and administrative issues.

While Rural Development does not have a specific emphasis for local food initiatives historically, the authorities governing many programs within RD have supported local food activities. Examples of existing programs and authorities within Rural Development currently support the objectives of local food initiatives include: Community Facilities Program (CF), Rural Business Development Grant (RBDG), Value Added Producer Grant (VAPG), Rural Cooperative Development Grant (RCDG), Small Socially Disadvantaged Group Grant (SDGG), Rural Cooperative Development Grant (RCDG), Renewable Energy for America Program (REAP), and the Business and Industry Loan Guarantee (B&I) program.

These programs have funded a wide array of community and local food projects. Examples include the development and implementation of food hubs, mobile slaughter units, farm-to-school programs, farmers markets, food banks, food cooperatives, food innovation centers, and value added agricultural products. RD promotes a range of interventions that expand the supply of and demand for nutritious foods, including increasing the distribution of agricultural products, developing and equipping grocery stores and strengthening the producer-to-consumer relationship.

Rural Development has actively promoted local and regionally produced agricultural food products. National Office staff regularly provide Field Office staff with information and guidance on how to apply programs to support this effort. Rural Development has worked to create an awareness of programs that can be used to support local and regional food projects. Further, RD has collaborated with both Agricultural Marketing Service and Food Safety Inspection Service to host webinars, produce articles and reports, and make presentations highlighting how programs can support local and regional food system efforts across Mission Areas. Staff has participated in numerous partner, stakeholder, and customer meetings where program information is shared and local and regional food success stories and replicable models are discussed. RD's Rural Cooperatives magazine has also been used to highlight multiple examples of local and regional food projects and how RD programs were used to support them.

*Question.* How do RBS programs provide opportunities for socially-disadvantaged farmers and groups?

*Answer.* RBS works to ensure that all eligible, rural residents are afforded access to the business, cooperative and energy program opportunities available through the agency.

RBS seeks to work with and assist socially disadvantaged farmers and groups. The Socially Disadvantaged Groups Grant (SDGG) program provides funding for cooperatives, groups of cooperatives and cooperative development centers whose governing board is comprised of at least 51 percent socially-disadvantaged members and whose primary focus is to provide technical assistance to socially-disadvantaged farmers and groups. Program funds are used for developing business plans, conducting feasibility studies, developing marketing plans and training. For example, World Farmers Inc. (WFI) located in Lancaster, Massachusetts, received a SDGG award to help a group of African immigrant farmers form a food cooperative for food production, marketing, and distribution. WFI is a nonprofit organization that provides technical assistance to small, socially disadvantaged and immigrant farmers. Client farmers are taught sustainable farming production, fair marketing principles,

and are mentored in the creation and operation of independent farming enterprises. WFI partners with the Flats Mentor Farm, also located in Lancaster, which acts as a farming incubator and who provides individual farm plots for the farmers to work on. At the farm, hands-on training is given in the technical aspects of farming, including farm safety and pest, weed and irrigation management among other farming issues.

The Value Added Producer Grant (VAPG) program also provides priority for beginning and socially-disadvantaged agricultural producers. The VAPG program provides planning and working capital grants to eligible producers for marketing value-added agricultural products. For example, Verdant Resources, Inc. in Duluth, Georgia used VAPG funds assist producers in the processing of ginger into various products. This VAPG project was designed to expand on an un-tapped locally grown market. Verdant Kitchen is processing and marketing products made from ginger and used VAPG funds to expand their base with a mass market retail campaign. They have a commercial processing facility in place and are working to expand the U.S. retail base for ginger products that currently are about 95 percent imported.

While not having specific focus or priority for socially-disadvantaged farmers and groups, RBS programs like the Rural Cooperative Development Grant, Rural Business Development Grant, Renewable Energy for America Program, and Delta Health Care Services have all been used to support and assist socially-disadvantaged producers and groups create or expand economic opportunities.

*Question.* How does RBS support start-up businesses, and small and mid-sized businesses?

*Answer.* As we know, entrepreneurs and small businesses are the engines of American innovation and our economic success. To maximize our competitive advantage as a nation, we must ensure that, with hard work, American entrepreneurs have the opportunity to find the capital, training, and market access they need to start and grow their businesses.

The Rural Business-Cooperative Service (RBS) supports startup, small, and mid-sized businesses through a number of programs. For example, the Value Added Producer Grant (VAPG) program provides priority for operators of small or medium sized farms or ranches structured as family farms and the Rural Microentrepreneur Assistance Program provides assistance to businesses with 110 or fewer employees. These and other RBS programs assisting start-ups and small to mid-sized businesses include:

- Intermediary Relending Program
- Rural Microentrepreneur Assistance Program
- Small Disadvantaged Groups Grant program
- Rural Business Development Grant program
- Rural Economic Development Loan and Grant program
- Rural Energy for America Program
- Value-Added Producer Grant program
- Business and Industry Guaranteed Loan program

Through such programs as these, RBS provides increased access to capital, job training, business development opportunities, strategic community planning, and other resources. In addition to the direct assistance we provide these businesses, our financial support is creating lasting economic development opportunities in the rural communities where the projects are located. Our programs, in other words, have made, and continue to make, a significant impact on rural communities. For example, since 2009, through over \$10.9 billion in investments, RBS programs are estimated to have helped over 103,000 rural businesses (over 60 percent of which are small businesses) start or expand their operations with over 440,000 jobs created or saved. In Fiscal Year 2015 alone, RBS programs are estimated to have helped over 12,500 rural businesses through \$1.5 billion in loans, loan guarantees, and grants.

*Question.* How does RBS support cooperatives?

*Answer.* Rural Development's Cooperative Programs has over 80 years of experience successfully working with the cooperative sector and remains the only Federal agency charged with that responsibility. Cooperative Programs currently works to support the 2,238 U.S. farmer, rancher, and fishery cooperatives who reported gross sales of \$235 billion in 2012.

When possible, RBS staff works to deliver direct cooperative development assistance. RBS has been also been effective in leveraging investments through the Rural Cooperative Development Grant (RCDG) program to build cooperative development capacity throughout the nation. For example, the Foundation for Agriculture, Innovation and Rural Sustainability (FAIRS) in Richmond, Virginia provides support to cooperatives and producers in developing and advancing their agricultural, economic and social interests to enhance their quality of life. Virginia FAIRS has received

funding from the Rural Cooperative Development Grant program to assist individuals, cooperatives, small businesses and other similar entities in rural areas to enable and assist cooperative and business development. For example, the Kohala Center, Inc. in Hawaii received a grant of \$200,000 to provide cooperative and business development technical assistance to rural areas throughout Hawaii to combat the physical isolation and dependence on imported food and energy. Funds will be used to provide technical assistance to agricultural producers, emerging food hubs, and local food distributors and linking them to local institutional buyers.

RBS continues to support Rural Cooperatives magazine, a bi-monthly USDA publication that continues to be an important communication tool with the cooperative community. The magazine regularly highlights successful cooperative operations and -examples of cooperatives using Rural Development in addition to discussing current issues and opportunities for cooperatives.

RBS maintains a library of approximately 200 information, education and research publications on the cooperative business model. In addition, RBS remains the sole provider of statistics on U.S. agricultural cooperatives. An annual survey of cooperatives allows RBS to maintain historic data and information and supports the production of the Directory of Cooperatives, Annual Cooperative Statistics Report and The Top 100 Agricultural Cooperatives. Additionally, RBS staff will regularly meet with international visitors to provide information and discuss cooperatives in the U.S.

In October 2015, Rural Development launched the Interagency Working Group on Cooperative Development (IWGCD). The IWGCD is comprised of representatives from Federal departments and agencies that support programs and services focusing on or, working with, cooperatives. The IWGCD will address programs affecting cooperatives and their development. The IWGCD will identify and engage key government, private, and non-profit organizations that play a role in improving the coordination and effectiveness of programs serving cooperative sectors. These partnerships and collaborations provide mechanisms to obtain feedback on how Federal initiatives are understood at the local level; keep organizations informed about Federal funding opportunities; and provide the IWGCD with communication channels to regional, state, and local programs.

---

#### QUESTIONS SUBMITTED BY SENATOR TOM UDALL

*Question.* Describe the role of your department Chief Information Officer (CIO) in the development and oversight of the IT budget for your department. How is the CIO involved in the decision to make an IT investment, determine its scope, oversee its contract, and oversee continued operation and maintenance?

*Answer.* The USDA CIO works closely with senior leadership both at the Department level and within the Bureaus and Staff Offices to consistently align USDA's budget, finance, acquisitions, human resources, and IT communities.

In addition, the USDA CIO ensures IT budget requests are approved by all agencies CFOs and CIOs.

The budget formulation process is focused on resource allocation decisions which may affect current and future acquisition programs. In order to be effective with this process, the CIO and Budget Officer will continue to work with senior policy officials, including the Secretary's Office, to identify resource needs in support of existing policy priorities and the Department's strategic goals and objectives. In addition, early engagement with the USDA Mission Areas, understanding their lines of business (LOBs) in order to have a cohesive synergy with the information technology communities and incorporating the CIO into the pre-planning process along with the CFO, and Budget Officer will ensure clear visibility into the prioritization of programs before any final decisions are submitted to start the approval of any budget formulation requests.

*Question.* Describe the existing authorities, organizational structure, and reporting relationship of the Chief Information Officer. Note and explain any variance from that prescribed in the newly-enacted Federal Information Technology and Acquisition Reform Act of 2014 (FITARA, PL 113-291) for the above.

*Answer.* Currently the Office of the Chief Information Officer (OCIO) is located within USDA's Departmental Management organization under the Assistant Secretary for Administration. The Department's CIO also reports to the Deputy Secretary in the management and oversight of USDA's Enterprise Information Technology Investment Review Board (E-Board) and also provides regular updates to the Secretary concerning USDA's IT portfolio.

*Question.* What formal or informal mechanisms exist in your department/agency to ensure coordination and alignment within the CXO community (i.e., the Chief In-

formation Officer, the Chief Acquisition Officer, the Chief Finance Officer, the Chief Human Capital Officer, and so on)?

*Answer.* USDA has developed a FITARA Common Baseline Plan that identifies CXO roles and responsibilities, process, procedures and policies focused on coordination and alignment within the CXO community. USDA has diagramed these procedures and processes, identified touch points between the CIO and existing CXO processes and procedures and worked with the CXOs to ensure CIO involvement. The revised processes and procedures are being captured and placed in existing departmental regulations, departmental notices, policies memorandums, etc.

*Question.* According to the Office of Personnel Management, 46 percent of the more than 80,000 Federal IT workers are 50 years of age or older, and more than 10 percent are 60 or older. Just 4 percent of the Federal IT workforce is under 30 years of age. Does your department have such demographic imbalances? How is it addressing them?

*Answer.* Yes. The CIO, in consultation with USDA's Chief Human Capital Officer (CHCO), is developing competency requirements and is enhancing its workforce planning framework for the recruitment and retention of all IT professionals.

*Question.* How much of the department's budget goes to Demonstration, Modernization, and Enhancement of IT systems as opposed to supporting existing and ongoing programs and infrastructure? How has this changed in the last 5 years?

*Answer.* Over the past 5 years USDA's IT budget has not significantly changed and as such the distribution of the IT budget between Development, Modernization, and Enhancements (DME) to Operations and Maintenance (O&M) has not seen a significant change. Based upon USDA's report to OMB via the IT Portfolio Summary DME is at 14 percent and O&M is at 86 percent.

*Question.* What are the 10 highest priority IT investment projects that are under development in your department? Of these, which ones are being developed using an "agile" or incremental approach, such as delivering working functionality in smaller increments and completing initial deployment to end-users in short, six-month timeframes?

*Answer.* USDA considers an IT investment as high priority if it has one or more of the following attributes: (1) Mandated by legislation or Executive Order; (2) Requires a common infrastructure investment; (3) Considered strategic or mandatory-use investments; (4) Differ from or greatly impact the Department's infrastructure, enterprise architecture or standards guidance; and (5) Involves multiple-agency funding. However as priorities evolve and other factors enter the equation or become mission-critical, additional attributes could become important in our definition.

Investment Name	Short Description	Agile or Incremental Development?
APHIS-Certification, Accreditation, Registration, Permitting, and Other Licensing (CARPOL).	To ensure that the certification, accreditation, registration, permitting, and other licensing strategies and operations of APHIS to make the best use of existing and emerging technologies, technology support, and end-user education.	Yes, an agile methodology is being leveraged.
DM-OCIO-Optimized Computing Environment (OCE).	OCE revitalizes the Service Center Agency (SCA) IT infrastructure. This multi-year initiative focuses on technological enhancements on all levels of the IT architecture (e.g., network and servers) with the purpose of supporting SCA modernization projects. The successful implementation of the projects within the investment will provide a more highly secure computing environment and platform allowing USDA to monitor events and protect against potential cyber threats.	No, as it is not a system development program but replaces hardware.
DM-OCIO-USDA Security Operations Center (SOC).	Investment to maintain USDA IT Security Operations Center (SOC) focused on achieving USDA Security Strategy: Achieve proactive security through actionable insight. A successful SOC relies upon continuous investment to ensure that its capabilities evolve in response to the evolving cyber threat environment. A SOC is a major cornerstone of a cybersecurity program. This investment is in place to upgrade, modernize the capabilities of the USDA SOC.	No agile methodology is being leveraged at this time.

Investment Name	Short Description	Agile or Incremental Development?
FSA-0111 Common Farm Programs Systems.	The purpose of this investment is to support the development and maintenance of a portfolio of core Farm Program applications and services used by Farm Programs, Farm Loans and Commodity Operations as well as other USDA Agencies. These systems include Acreage Reporting & Compliance Systems, Farms Programs Management Systems, Customer Name/Address Systems (including SCIMS), Representative Link Manager System, Subsidiary Systems and Common Payment Program.	Yes, an iterative methodology is being leveraged.
FSA-103 .....	Consolidated Farm Loan Program Information & Delivery Systems This investment supports FSA's Farm Loan Program (FLP) and its goal of providing capital to American farmers and ranchers by providing them with ownership, operating, and emergency loans through streamlined and modernized processes and systems.	Yes, an iterative methodology is being leveraged.
FSIS-Public Health Information System (PHIS).	PHIS established to develop an effective food safety system that can collect, assess and provide information enabling a response to food safety hazards. FSIS adopted the public health-based approach that is in line with the core food safety principles of the President's Food Safety Working Group. PHIS is a modern, coordinated food safety system which helps prevent harm to consumers and uses good data and analysis for effective food safety inspections and enforcements.	Yes, an iterative methodology is being leveraged.
NRCS-Conservation Delivery Streamline Initiative (CDSI).	NRCS has initiated CDSI with the purpose of implementing a more effective, efficient and sustainable business model for delivering conservation assistance across the Nation. This initiative has three objectives: 1) Simplify Conservation Delivery for customers and employees; 2) Streamline Business Processes to increase efficiency and integration across business lines; and 3) Ensure Science-based Assistance to reinforce the delivery of technically sound products and services.	Yes, an agile methodology is being leveraged.
RD-Comprehensive Loan Program.	The CLP initiative was launched to modernize and streamline the application delivery portfolio in order to better serve RD's citizen beneficiaries, and to provide RD employees with the technology and tools they need to pursue RD's mission. RD offers a variety of direct and guaranteed loan programs for Single Family (SF) and Multi-Family (MF) Housing, Business, Community Facilities, and Utilities programs.	Yes, an incremental methodology is being leveraged.
RMA-13 Emerging Information Technology Architecture (EITA).	This investment houses RMA's financial, insurance, risk management, and actuarial applications. This investment is essential to mission critical to the Federal Crop Insurance Corporation and the Risk Management Program. This investment supports the reengineering of all business & financial systems associated with delivery of the crop insurance program.	Yes, an agile methodology is being leveraged.

Investment Name	Short Description	Agile or Incremental Development?
FNS-Supplemental Nutrition Assistance Program (SNAP) Support.	This investment consists of following systems/applications: (a) Systems SNAP Quality Control System (SNAPQCS) supports FNS efforts to determine the error rate by each State, to monitor and reduce State error rates for SNAP, and minimize erroneous payments. Error rate determination is required by legislative requirements. (b) Electronic Disqualified Recipient Subsystem (e-DRS) is used to store information on disqualified recipients of SNAP benefits. The function of e-DRS is mandated by legislative requirements. Every state must ensure that disqualified recipients are not let back into the program. (c) SNAP Workflow and Information Management (SWIM)—SWIM is a new system that is currently under development. It will automate the SNAP key business functions of waiver processing and policy clarifications. The ability to submit SNAP related waiver requests, policy clarifications, manage work related to submitted requests/clarification, search for information, and report on information in a user-friendly and intuitive interface. (d) Treasury Offset Program (TOP)—is a centralized offset program, administered by the Bureau of the Fiscal Service's (Fiscal Service) Debt Management Services (DMS), to collect delinquent debts owed to Federal agencies and states. (e) Retailer File Solution (RFS) (f) SNAP Retailer Locator (g) Healthy Access Locator (h) SNAP Policy WIKI.	Yes, an agile methodology is being leveraged.

*Question.* To ensure that steady state investments continue to meet agency needs, OMB has a longstanding policy for agencies to annually review, evaluate, and report on their legacy IT infrastructure through Operational Assessments. What Operational Assessments have you conducted and what were the results?

*Answer.* The USDA Capital Planning and Investment Control (CPIC) process assesses each investment's impact on mission performance, to identify any needed investment changes or modifications, and to revise the investment management process based on lessons learned. An Operational Analysis (OA) is performed by the Program/Project Manager after a year of the investment being in operations, and updated on an annual basis. The results from these activities determine the investment's efficiency and effectiveness in meeting performance and financial objectives. Additionally, OCIO conducts annual portfolio reviews on the agencies and staff offices to evaluate their portfolio to provide further insight into legacy IT infrastructure and IT systems.

*Question.* What are the 10 oldest IT systems or infrastructures in your department? How old are they? Would it be cost-effective to replace them with newer IT investments?

*Answer.*

Investment Title	Year
Initiated FS-Automated Timber Sale Accounting .....	1980
FSA-107 Consolidated General Sales Manager (CGSM) .....	1982
FS-Forest Service Computer Base .....	1983
FSA-105 Conservation Systems .....	1985
FSIS-USDA Meat & Poultry Hotline (Hotline) .....	1985
FSA-0100 Commodity Management Systems .....	1987
FSA-0101 Price Support Systems .....	1987
FSA-106 Consolidated Financial Management Information Systems (CFMIS) .....	1987
FSA-009 Cotton Management System (CMS) .....	1988
DM-OC-Ongoing IT Support .....	1993

USDA manages multiple systems in program investments and tracks which systems are scheduled to be decommissioned as new capability becomes available. When USDA makes modernization decisions, we look for opportunities to create investments that will modernize or consolidate a number of related systems. The Animal and Plant Health Inspection Service (APHIS) CARPOL (Certificates, Accredita-

tions, Registrations, Permits, and Other Licenses) system, for example, will consolidate more than eight separate systems that support the safe introduction and movement of regulated agricultural products.

*Question.* How does your department's IT governance process allow for your department to terminate or "off ramp" IT investments that are critically over budget, over schedule, or failing to meet performance goals? Similarly, how does your department's IT governance process allow for your department to replace or "on-ramp" new solutions after terminating a failing IT investment?

*Answer.* The USDA's Integrated Information Technology Governance Framework (IITGF) is a holistic set of processes, procedures, and guidelines that assist the Office of the Chief Information Officer's (OCIO's) customers to improve mission delivery. Through this framework the CIO actively engages with all key stakeholders involved in the governance structure consisting of an Integrated Advisory Board that makes recommendations on IT investments to the executive-level E-Board, chaired by the USDA's Deputy Secretary. Composed of the Department's senior leaders, the E-Board ensures that existing and proposed IT investments contribute to the Secretary's strategic vision and mission requirements, employ sound IT investment methodologies, comply with Departmental enterprise architecture, employ sound security measures, and provide the highest return on the investment or acceptable project risk. The E-Board provides the Secretary with recommendations for review and decision authority. These recommendations, based on whether an investment is meeting value (cost), schedule, strategic alignment, risk management, and performance goals, may well precipitate that an investment is "off ramped", paused, or terminated. Similarly, this governance structure provides the flexibility to "on ramp" new, innovative solutions that are replacing investments that have been paused or terminated.

*Question.* What IT projects has your department decommissioned in the last year? What are your department's plans to decommission IT projects this year?

*Answer.* The Department does not conduct decommissioning plans on IT projects. We conduct decommissioning plans at the IT system level and investment level. USDA has decommissioned twenty-three (23) investments. During USDA annual portfolio reviews, it is discussed what investments/projects will be decommissioned for the next OMB budget year submission. All investments that will be decommissioned, complete a Decommission Plan and get approval from the Associate Chief Information Officer of Information Resource Management. This process is built within our Integrated IT Governance Framework.

*Question.* The newly-enacted Federal Information Technology and Acquisition Reform Act of 2014 (FITARA, PL 113-291) directs CIOs to conduct annual reviews of their department's IT portfolio. Please describe your department's efforts to identify and reduce wasteful, low-value or duplicative information technology (IT) investments as part of these portfolio reviews.

*Answer.* USDA currently has been annually reviewing the USDA portfolio and all of the component portfolios for the past 3 years. The Department's enterprise information technology governance program, portfolio reviews, and Enterprise Architect program identify and reduce wasteful, low value, or duplicate information technology investments.

*Question.* In 2011, the Office of Management and Budget (OMB) issued a "Cloud First" policy that required agency Chief Information Officers to implement a cloud-based service whenever there was a secure, reliable, and cost-effective option. How many of the department's IT investments are cloud-based services (Infrastructure as a Service, Platform as a Service, Software as a Service, etc.)? What percentage of the department's overall IT investments are cloud-based services? How has this changed since 2011?

*Answer.* The Department has an investment process to support assessment of Cloud capability. In the recent months the USDA CIO has promoted more adoption of Cloud solutions and movement towards a more innovative approach leveraging the capabilities of Cloud technologies. Of the current 202 investments, approximately 23 or 11 percent are currently leveraging a cloud-based service and an additional 26 investments evaluated a cloud-based solution an alternative. USDA did not track this information in 2011, but during infiscal year 2012, USDA's percentage of investments that leverage a cloud-based solution was 13 percent of the 308 investments.

*Question.* Provide short summaries of three recent IT program successes—projects that were delivered on time, within budget, and delivered the promised functionality and benefits to the end user. How does your department define "success" in IT program management? What "best practices" have emerged and been adopted from these recent IT program successes? What have proven to be the most significant barriers encountered to more common or frequent IT program successes?

*Answer.* The USDA OCIO defines “successful” IT projects or investments as those that 1) meet business requirements, 2) are delivered and maintained on schedule, 3) are delivered and maintained within budget, and 4) deliver the expected business value and return on investment. The USDA OCIO notes that many factors contribute to a successful project or investment, but the USDA has found that effective project management and governance practices are particularly crucial. The USDA differentiates between “project management success” (i.e. delivering in accordance with the agreed project objectives) and “product success” (i.e. the amount of value the project’s deliverables bring once the project is over). USDA believes that some key factors or barriers to success often contribute to the failure of a project, such as:

- Lack of stakeholder/user input
- Incomplete and/or vaguely defined requirements or specifications
- Changing requirements or specifications
- Lack of executive support
- Insufficient planning
- Underestimated time and/or resources allocated for design, development, quality assurance, and/or quality control
- Technological incompetence
- Insufficient resources
- Unrealistic expectations
- Unclear objectives
- Unrealistic timeframes
- New or untested technology

However, the USDA notes several factors that are crucial to the success of any IT project or investment, such as:

- Clear and clearly articulated goals
- Comprehensive, long-term, and detailed planning
- Early definition of deliverable quality criteria
- Active executive support with a shared vision throughout the project’s life
- Carefully planned implementation
- Concise, consistent, complete, and unambiguous business and technical requirements
- Realistic estimates and schedules
- Early risk analysis and ongoing risk management
- Planning for business process change management
- Adherence to a formalized IT governance approach and framework
- Proactive issue resolution
- Stakeholder involvement throughout the life cycle
- Defined and consistently executed change management to minimize scope increases
- A skilled, certified Project Manager experienced in the execution of project management best practices
- Execution of a formal system development methodology (such as the Agriculture’s System Development Life Cycle, AgSDLC)
- A commitment to success

These three successful investments are still continuing with their implementations and have released incremental functionality to their customers:

1. Animal, Plant and Health Inspection Service (APHIS) Certification, Accreditation, Registration, Permitting and Other Licenses (CARPOL)

a. APHIS CARPOL successfully delivered a single system, cloud-based platform to support permitting live dog imports that is required by a Congressional amendment to the Animal Welfare Act. The tool reduces the processing time from days to hours and will allow anyone to apply for a permit to bring a live dog(s) into the continental U.S. or Hawaii, for the purpose(s) of research, resale, or veterinary treatment.

2. Natural Resource and Conservation Service (NRCS) Conversation Delivery Streamlining Initiative (CDSI)

a. NRCS CDSI successfully released one of three modules using the agile methodology called Conservation Client Gateway (CCG). Conservation Client Gateway is a new NRCS public website that provides individual landowners and land users the option to request conservation technical and financial assistance from NRCS.

3. OCIO Identity Credential Access Management (ICAM).

a. OCIO ICAM successfully implemented the personal identification verification (PIV) initiative by securing our applications behind the identity access tool to enable customers to access multiple applications with a single credential. The implementation of the PIV provides for the use of multi-factor authentication, a key tool in our cybersecurity program.

*Question.* A June 2015 Government Accountability Office (GAO) report found that USDA spent about \$423 million since 2004 to modernize IT systems through Modernize and Innovate the Delivery of Agricultural Systems (MIDAS) before halting the program due to poor performance and uncertainty regarding future plans. GAO made five recommendations to the USDA Farm Service Agency (FSA), including establishing and implementing a plan for adopting recognized best practices for program management. Has FSA fully implemented these five recommendations? Please explain how USDA implemented each GAO recommendation.

*Answer.* GAO provided five interrelated recommendations to improve the selection, planning, and control of IT projects results. FSA has taken immediate steps to improve IT internal controls in the areas of integrated capital planning, IT governance, risk management, project management, Cybersecurity and other IT oversight initiatives. FSA created an Investment Review Board, an executive level governance board that meets regularly to assess and prioritize IT investments. In addition, an external contractor has been engaged to perform an independent third-party assessment to determine if the current enterprise solution provides the necessary functionality and is the most cost effective modernization solution.

*Question.* The Federal IT Dashboard is a website that allows the general public to view details of Federal information technology investments. This transparency tool shows that the USDA “NFC Shared Services—IT Systems” investment as rated “red” or high risk. Since August 2014, various Chief Information Officer comments published on the Dashboard have indicated that USDA is conducting a baseline review to improve this investment’s cost and schedule performance. What actions has USDA taken to remediate the NFC Shared Services—IT Systems investment’s troubled performance? Have these steps improved this investment’s cost and schedule performance to a point where it can be rated “green?”

*Answer.* Since June 2015, the NFC Shared Service Investments has been rated RED due to numerous issues based on the criteria established by OMB which is used to rate all Major Investments. The issues include lack of program management artifacts, lack of EVM reporting, and DM&E reporting.

On June 24, 2015, the USDA CIO and Senior Executives held a Portfolio Review with OCFO-NFC, which included in depth analysis of the NFC Shared Service Investments. In the portfolio review it was determined that the USDA CIO designees would travel to New Orleans to discuss the requirements of Earned Value Management (EVM), Capital Planning and Investment Control (CPIC) requirements and Information Technology Governance process. OCIO worked with the NFC Investment team to capture performance data regarding their projects and activities that are a part of the NFC Shared Service Investments. From 16 through 18 September 2015, the Capital Planning & IT Governance Division (CPIGD) Director and CPIGD Analyst met with all NFC Senior Executives and the NFC Program/Project Managers (PPMs). During the meetings the USDA OCIO team identified the above-stated issues and developed a corrective action plan (CAP), which was provided to the OCFO-NFC Investment team. Once the OCFO-NFC Investment team accomplishes the corrective actions, USDA OCIO will reevaluate the NFC Shared Service Investments.

Since the three days of meetings, OCFO-NFC Investment team started the following actions to improve their score to yellow for the November 2015 monthly on the Federal IT Dashboard:

1. Reporting all projects, activities, and risks within their business case.
2. Updated the business case contract table.
3. Identified and is now reporting the line of funding for all shared services agencies and staff offices.
4. Provided an updated Risk Management Plan and is in the process of updating investment Acquisition Plan and Investment Charter.

On October 27, 2015 the USDA OCIO EVM Manager and CPIGD Analyst have met with NFC Investment team to discuss how they can conduct EVM and rebaseline the investment. USDA OCIO scheduled a series of follow-up meetings with OCFO-NFC team to finalize and have NFC complete this process, which include monthly major investments to discuss IT Dashboard scores and outstanding issues in order to improve the performance of the NFC investments and eventually achieve a green status.

NFC will be undergoing a reorganization within their office to better serve the mission and support of their functions. A new CIO has now been assigned to NFC that will ensure the investment will be better managed. NFC will be executing a Request For Proposal (RFP) that will include an EVM clause for support and assist with them reporting EVM to the USDA OCIO Department. Once EVM is being reported and they have finalized the updates to the investment artifacts as well as

continuing to manage, monitor, track and update their projects, activities, risks and performance metric they should be able to move to a green status.

---

QUESTIONS SUBMITTED BY SENATOR PATRICK LEAHY

*Question.* In many ways, Vermont highlights both the successes and challenges of ensuring that rural America has access to affordable and quality broadband service. Burlington has a vibrant start-up community and is home to successful online businesses like Dealer.com. Traditional small businesses like the Vermont Country Store have augmented their reach and built meaningful 21st Century brands by operating popular online stores. Unfortunately, I still hear too often from Vermonters who lack access to broadband service and the transformative opportunities that it brings. I worry that without aggressive action to spur investment in rural areas, we will leave these Americans even further behind as the next generation of broadband service is deployed.

Do you agree that access to quality and affordable broadband is no longer a luxury but a necessity in rural America?

*Answer.* Yes, we agree that broadband is now a necessity. Children in rural America as well as children everywhere must have broadband access to do homework and their lessons. Without easy access rural children will fall way behind their counterparts in urban and suburban areas as well as the rest of the world.

In addition, rural America is doing more and more ecommerce and broadband service is necessary to facilitate this.

Farmers now use the Internet to sell their crops and auction their cattle worldwide. They also use broadband to control how their tractors plow and when and how much to water their fields.

The Federal Communications Commission's (FCC) 2015 broadband progress report found that rural America is underserved at every broadband speed, with 20 percent lacking access even to the minimum acceptable level of broadband service Congress set for the Farm Bill Loan Program in 2014. In contrast, the FCC's report found that 92 percent of urban Americans have access to speeds that are more than 6 times higher than that minimum standard.

*Question.* What more can we do to close this rural/urban broadband divide?

*Answer.* Utilizing programs like the RUS Community Connect Grant Program is one way to get broadband service to the neediest areas. The areas with no service today are some of the most rural, low density areas in the country. It is difficult to support a business plan in these areas a grant funding could be a key component. We must also work with existing service providers and help them understand that there are ways to serve these rural areas and still make a profit.

As we have done in the past to support universal service for voice services, we must now refocus our efforts and support mechanisms to fully support the deployment of broadband service to every person in the country.

---

QUESTIONS SUBMITTED TO ADMINISTRATOR TONY HERNANDEZ

QUESTIONS SUBMITTED BY SENATOR PATRICK LEAHY

SECTION 515 MULTIFAMILY LOAN PROGRAM

*Question.* Throughout the country, thousands of properties participating in the Section 515 Multifamily Loan Program are approaching their 40-year terms, resulting in maturing mortgages that will no longer guarantee rent subsidies, threatening many low-income tenant households with drastic rent increases. This year, the affordability of 60 properties across the country, totaling more than 700 units, are threatened.

In my home state of Vermont, there are 79 active Section 515 properties containing 1,842 units that will expire within the next 10 years. Meanwhile, the statewide vacancy rate rests at one percent, making every unit assuring affordability even more critical to our housing stock.

This year, Lebanon, New Hampshire, is faced with losing 50 units of local affordable housing due to mortgage expiration at the end of the year. Twin Pines Housing Trust, a local affordable housing nonprofit organization serving Vermont and New Hampshire, was committed to continuing to serve the need for affordable housing in that area. Thankfully, with the help of the VT-NH State Rural Development Office, Twin Pines was able to successfully negotiate a purchase of the 50 units from the property owner, ensuring perpetual affordability to its residents.

I commend our Vermont-based partners for their commitment to this mission, but recognize that not all states and communities have motivated local housing providers with the necessary tools to preserve this critical housing stock. Looking ahead to the remaining contracts, there is an urgent need to address the potential loss of thousands of affordable housing units and provide necessary protections for low-income populations at risk of homelessness.

What plan does the Department currently have in place to address maturing mortgages in the immediate future, and over the next several years?

*Answer.* RD is very concerned with the potential loss of affordable housing as our Section 515 direct loans mature, because that housing may be lost in the community and the rental assistance support will no longer be available to the families in that property. If that RD housing is lost, the very low income families living there may have no other affordable housing in which to live.

In response, RD has provided a number of options for owners to keep their RD loan and protect the families living there.

- The borrower can apply through RD's Preservation NOFA for a deferral of their maturing mortgage for up to 20 years;
- The borrower can receive priority points if they choose to apply for both the deferral and additional RD funding for rehabilitation of property;
- The borrower can request a re-amortization and modification of the maturing loan to extend the loan term up to 20 years;
- If owners go through the prepayment process, their tenants may be eligible to receive housing vouchers.
- RD has also proposed legislation in the 2016 budget to extend housing voucher protection to tenants in properties with a mortgage that matures and the owner is not willing to extend the affordable housing feature of that property.

*Question.* When should housing providers and nonprofit partners expect to receive a plan from the Department so that they may properly plan for necessary purchase and sales agreements?

*Answer.* Throughout 2015, RD has participated in a series of public meetings with all stakeholders, including housing providers and nonprofit partners, to inform them of our efforts to retain our affordable housing. These sessions have included information regarding the use of Section 515 funds to finance the nonprofit acquisition of Section 515 properties in danger of being lost through mortgage maturity or prepayment. Our communications with stakeholders have begun to generate results—for example, late in fiscal year 2015, RD provided a \$6.7 million Section 515 loan to a nonprofit in New Hampshire to retain 100 units of affordable housing.

*Question.* What additional resources is the Department currently dedicating to address the immediate needs? And, will the Department be including funding requests in future budgets to address this issue?

*Answer.* In fiscal year 2015, RD made the decision to prioritize the use of Section 515 funds to finance the acquisition of Section 515 properties at risk of leaving the program through either prepayment or maturity of the existing mortgage. In fiscal year 2015, RD received an appropriation of \$28 million. Of this amount, RD used more than \$11 million to assist nonprofits in the acquisition of Section 515 properties in California, New Hampshire, and Pennsylvania. The remainder was used for the Multi-family Preservation and Revitalization program. RD's fiscal year 2016 proposed budget includes a request for an additional \$15 million in Section 515 funding for the preservation or construction of affordable housing; one of the purposes of the additional funding would be to retain existing affordable housing through the nonprofit acquisition process.

*Question.* In instances when mortgages expire and properties no longer guarantee rentals subsidies, is the Department considering options that would allow residents to remain in their homes and maintain the affordability, similar to the enhanced vouchers utilized by the Department of Housing and Urban Development? If not, why?

*Answer.* In addition to the steps the Department has taken to encourage property owners to remain in the RD portfolio through loan re-amortization and modification, and use of the MPR tools, the Department has also offered Letters of Priority Entitlement to tenants in maturing mortgages. Holding this Letter will allow the tenant to be placed at the top of the waiting list for any RD property in order to continue living in affordable housing. The Agency may be authorized to transfer the unused rental assistance to a new RD property in limited circumstances. The Department has also included in the fiscal year 2016 President's Budget a legislative proposal to allow Rural Development housing vouchers to be used by tenants in these maturing mortgage properties. Current voucher program appropriations language limits use to tenants in situations where the owner is prepaying the RD mortgage.

## CONCLUSION OF HEARINGS

Senator MORAN. With that, I thank, again, everyone for their attendance, and bring this hearing to a conclusion.

We are adjourned.

[Whereupon, at 12:15 p.m., Wednesday, October 21, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]



## LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

	Page
Baldwin, Senator Tammy, U.S. Senator From Wisconsin, Questions Submitted by .....	108
Blunt, Senator Roy, U.S. Senator From Missouri, Questions Submitted by .....	35
Boisvert, Brian, Chief Executive Officer and General Manager, Wilson Communications:	
Prepared Statement of .....	198
Statement of .....	197
Chrisman, Tony, Vice President and Owner, Chrisman Development Inc.:	
Prepared Statement .....	204
Statement of .....	203
Cochran, Norris, Deputy Assistant Secretary for Budget, Department of Health and Human Services .....	1
Cochran, Senator Thad, U.S. Senator From Mississippi, Statement by .....	179
Collins, Senator Susan M., U.S. Senator From Maine, Question Submitted by .....	84
Daines, Senator Steve, U.S. Senator From Montana, Questions Submitted by .....	42, 85
Feinstein, Senator Dianne, U.S. Senator From California, Questions Submitted by .....	47, 97
Hamburg, Hon. Dr. Margaret A., Commissioner, Food and Drug Administration .....	1
Prepared Statement .....	2
Summary Statement .....	4
Hernandez, Tony, Administrator, Rural Housing Service .....	159
Questions Submitted to .....	247
Hoeven, Senator John, U.S. Senator From North Dakota, Questions Submitted by .....	223
Leahy, Senator Patrick J., U.S. Senator From Vermont, Questions Submitted by .....	48, 104, 153, 247
Lowry, Stuart, President and Chief Executive Officer, Sunflower Electric Power Association .....	192
Prepared Statement of .....	194
Statement of .....	192
McBride, Brandon, Administrator, Rural Utilities Service .....	159
Questions Submitted to .....	223
McConnell, Senator Mitch, U.S. Senator From Kentucky, Questions Submitted by .....	39
Mensah, Hon. Lisa, Under Secretary for Rural Development .....	159
Prepared Statement of .....	164
Questions Submitted to .....	218
Summary Statement of .....	161
Merkley, Senator Jeff, U.S. Senator From Oregon:	
Questions Submitted by .....	43, 86, 150, 224
Statements of .....	3, 117, 161
Moran, Senator Jerry, U.S. Senator From Kansas:	
Opening Statements of .....	1, 51, 115, 159
Prepared Statements of .....	2, 51, 116, 160
Questions Submitted by .....	33, 81, 146, 218
Johansson, Dr. Robert, Acting Chief Economist .....	51
Ostroff, Hon. Dr. Stephen Ostroff, Acting Commissioner, Food and Drug Administration, Department of Health and Human Services .....	

	Page
Ostroff, Hon. Dr. Stephen Ostroff, Acting Commissioner, Food and Drug Administration, Department of Health and Human Services—Continued	115
Prepared Statement .....	120
Summary Statement of .....	118
Rikkers, Samuel, Acting Administrator, Rural Business-Cooperative Service ..	159
Simpson, William, Director of Legislative and Regulatory Affairs, National Rural Water Association:	
Prepared Statement .....	190
Statement of .....	188
Taylor, Michael, Deputy Commissioner for Foods and Veterinary Medicine; Food and Drug Administration .....	115
Tootle, William, Director, Office of Budget, Food and Drug Administration .....	115
Tyler, Jay, Chief Financial Officer, Food and Drug Administration .....	1
Udall, Senator Tom, U.S. Senator from New Mexico, Questions Submitted by .....	240
Vilsack, Hon. Thomas J., Secretary .....	51
Prepared Statement .....	52
Summary Statement .....	52
Young, Michael L., Budget Officer .....	51

## SUBJECT INDEX

	Page
DEPARTMENT OF AGRICULTURE	
Additional Committee Questions .....	81
Adequacy of the Thrifty Food Plan .....	100
Agricultural Research Service .....	104
Air Tankers .....	98
Animal Welfare Act .....	100
Antimicrobial Research .....	98
APHIS Overall Budget Priorities .....	87
ARC/PLC Signups .....	63
Assistance to Drought Impacted Communities in California .....	101
Avian Influenza .....	75, 88
Big Data .....	73
Bioenergy Program for Advanced Biofuels .....	65
Biotech Review in APHIS .....	83
Broadband Program .....	93
Budget:	
Reconciliation .....	104
Savings .....	80
Community Facilities Grants .....	94
Conservation .....	64
Technical Assistance .....	58
Consolidation of Food Safety Agencies .....	85
Colonias Communities .....	70
Crop Insurance .....	59
Cuba .....	81
Dietary Guidelines .....	57
Disruption in Poultry Trade .....	76
Electronic Access to Records .....	75
Environmental Concerns Within the Dietary Guidelines .....	85
Farm Service Agency Funding .....	62
Food:	
For Progress .....	96
Insecurity in Military Households .....	102
Safety Modernization Act .....	105
Forest Management .....	113
Implementation of New Methods of Poultry Slaughter Inspection .....	83, 88
Innovation Institute for Cellulosic Nano-Materials .....	77
IT Modernization .....	82
Healthy Foods Financing Initiative (HFFI) .....	86
Housing Vouchers .....	92
Local Food Systems .....	64
Local and Regional Procurement .....	95
Margin Protection Program for Dairy .....	108
Merging Food Safety Responsibilities .....	89
Military Families Receiving Snap Benefits .....	102
Midas Program .....	74
Mobile Slaughter Facilities .....	78
Multi-Family Housing Preservation Pilot .....	91
National:	
Organic Program Sunset Policy Change .....	113
Standards Board Recommendations .....	106

	Page
OIE Standards .....	76
Organic Research .....	111
Pathogen Standards .....	97
Pollinators .....	60
Port of Vancouver Grain Inspections .....	71
Potato Wart .....	84
Public Law 480, Title I .....	78
Rental Assistance .....	61, 90
Rice Entering China .....	84
Rural:	
Child Poverty Pilot Initiative .....	94
Energy Savings Program .....	60
Housing .....	105
Outmigration .....	63
Safety Reports .....	72
School:	
Equipment Grants .....	68
Meal Standards .....	80
Self-Help Housing Program.....	77, 93
Specialty Crop Pest Program .....	99
Subcommittee Recess .....	114
Summer:	
Feeding Program .....	78
Electronic Benefit Transfer (EBT) Demonstration Projects .....	103
Tree and Forest Pests .....	107
USDA:	
Assistance to California .....	97
Wildlife Services .....	107
U.S. Sheep Experiment Station .....	86
Water of the U.S. Rule .....	73
Waters Infrastructure .....	69
Wildfires in California .....	98
Yazoo River Basin .....	79

#### A REVIEW OF RURAL DEVELOPMENT IN 21ST CENTURY AMERICA

Additional Committee Questions .....	218
Broadband .....	235
Access.....	171, 180
And Underserved Communities .....	178
Opportunity Council Recommendations .....	181
Service in Tribal Areas .....	179
EPA Rules .....	185
Loan Portfolio Credit Quality .....	230
Maturing Mortgages .....	227
Multi-Family Housing Preservation Pilot .....	228
New Poverty Pilot Program .....	229
Partnerships .....	173
Private Investment in Rural Infrastructure .....	225
Program Duplication .....	173
Rental:	
Assistance .....	226
Program .....	175
2015 Shortfall .....	182
Rural:	
Development Visibility .....	169
Energy for America Program (REAP) .....	236
Energy Saving Program (REAP) .....	224
Housing:	
Maturing Mortgages .....	219
502 Direct Loans .....	219
Section 502 Guaranteed .....	220
Section 538 Eligibility for Housing Cooperatives .....	220
Energy Savings Program (RESP) .....	224
In Character .....	220
Utilities Administrator Brandon McBride .....	223

	Page
—Continued	
Utility Service—Existing Water and Waste Disposal Loan Portfolio .....	221
Section:	
515 Multifamily Loan Program .....	247
515 Rural Rental Housing .....	218
Sequestrations Impact .....	186
Single Family Housing Direct Loan Program .....	229
Strategic Economic and Community Development Interim Rule .....	222
Sustantially Underserved Tribal Areas Program .....	187
Universal:	
Service .....	201
Fund .....	176

---

#### FDA FOOD SUPPLY SAFETY EFFORTS

Additional Committee Questions .....	146
Animal:	
Feed .....	147
Rule .....	142
Antibiotics in Products .....	135
Budget Request .....	144
California Produce .....	133
Compliance .....	128
Cucumber Salmonella Outbreak .....	133
Domestic and Imported Foods .....	136
FSMA .....	115, 119
And Foreign Suppliers .....	130
Collaboration .....	140
Coordination with USDA .....	134
Funding .....	116
Implementation Plan .....	128
Spending .....	144
Food:	
Illness Deaths .....	136
Safety .....	117, 118
Foreign Inspections .....	131
Guidance .....	130
Import Safety .....	148
Inspection .....	128
Partnerships .....	128
Preventive:	
Control Rules .....	120
And Trace Ability .....	140
Produce Safety .....	146
Reprioritizing Funding .....	145
Risk Assessments for Soft-Ripening and Raw Milk Cheese .....	156
Salmonella in Peanut Butter Outbreak .....	139
State Budget Concerns .....	153
States Role in FSMA Implementation .....	142
Support for Farmers .....	154
Vibrio Incidence .....	138

---

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

Additional Committee Questions .....	33
Biosimilars .....	35
Budget Request .....	5
Dietary Guidelines .....	13, 21, 49
Drug Safety Labeling .....	10
Ebola Emergency Appropriations .....	13
E-Cigarettes .....	15
Electronic Drug Inserts .....	46
Expanded Access Request .....	27

	Page
Imported Food Inspection .....	43
FDA:	
Food Safety Activities .....	39
Office of Regulatory Affairs (Field Staff) Reorganization .....	45
Oversight of Antibiotic Use and Resistance .....	47
Food:	
And Drug Administration .....	1
Inspections .....	20
Safety .....	9, 19
Centers of Excellence .....	46
Modernization .....	31, 48
Act .....	22
Rules .....	30
Generic Drugs .....	17
Imported Food Inspection .....	43
Irrigation Water Standards .....	25
Maple Ingredient Labeling .....	11
Menu Labeling.....	16, 23
Mobile Medical Applications .....	17, 29
Right to Try Laws .....	28
State Inspection Standards for FSMA .....	43
Statutory Role of the Food and Drug Administration .....	12
Tobacco Deeming Regulation .....	14
Untitled Letters .....	37